tise transition, innovation and sustainability environments

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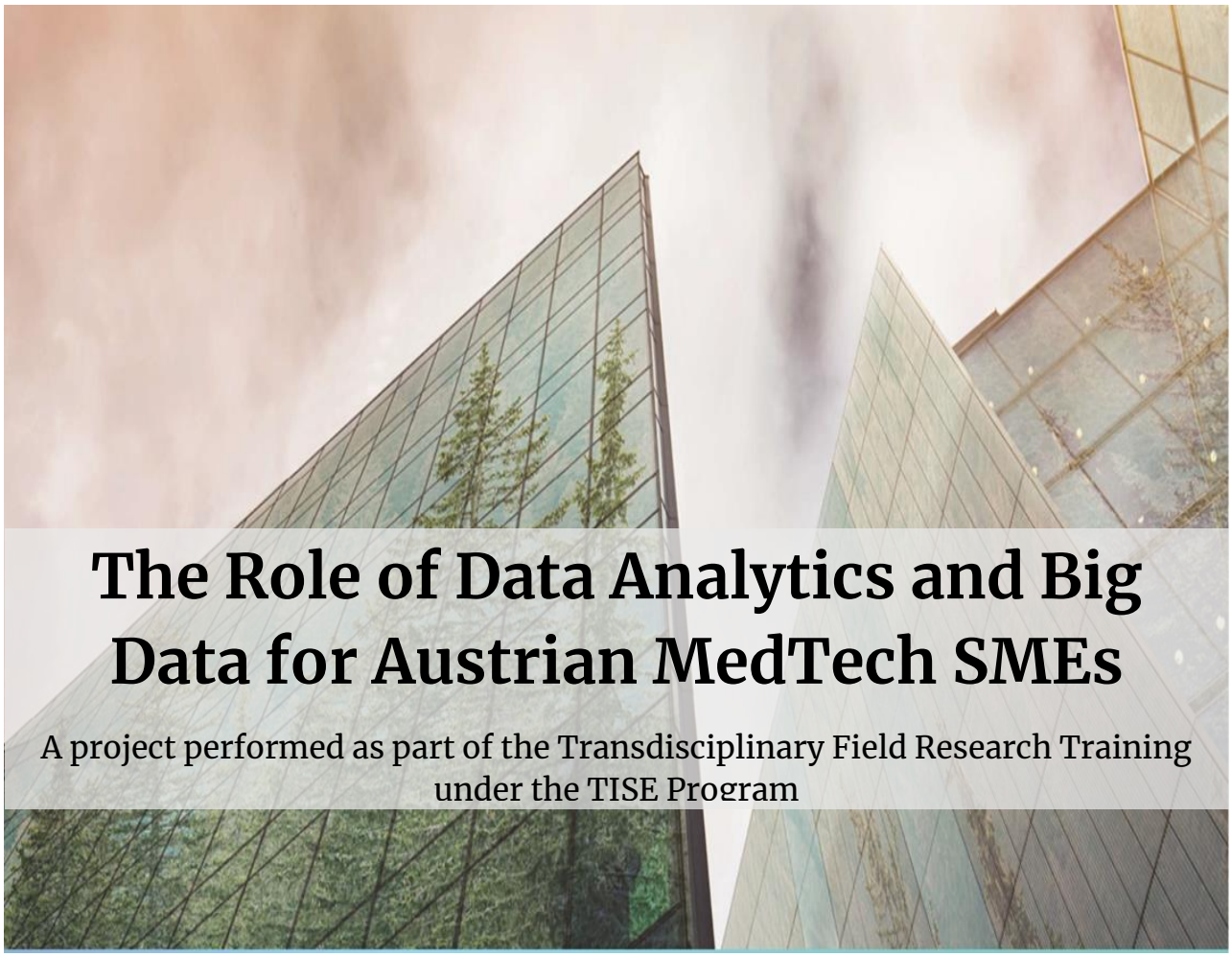

The Role of Data Analytics and Big Data for Austrian MedTech SMEs

A project performed as part of the Transdisciplinary Field Research Training under the TISE Program

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Date: 7th April 2023

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List of Contents

1. Intro: What is the Td-Problem (derivation of the Guiding Question)

Small and Medium Enterprises are a fundamental part of the Austrian economy, constituting almost 99.6% of all the national companies in 2020, with an added value of 134 billion euros („SME DATA“, o. J.). However, in relation to digital technologies, Austrian SMEs are overall less advanced than the European average. These companies are using Big Data comparatively less than their European counterparts, 8% compared to 14% of SMEs EU-wide (Bundesministerium für Digitalisierung und Wirtschaftsstandort, 2022). To enforce its digitalisation Austria created six Digital Innovation Hubs with a network that shares expertise and provides infrastructures to the SMEs, allowing direct access to partners from research and business (Bundesministerium für Digitalisierung und Wirtschaftsstandort, 2022).

In 2020 the Austrian Medical Technology Sector recorded 577 registered Businesses (Statista, 2022) and a revenue of 9 Billion Euros (Statista, 2022). Statista describes medical technology as hospital technology and medical equipment such as computer tomographs, dialysis machines and pacemakers Austria's high demand for medical technology is mainly met by imports from Germany. It obtains half of its imports from its neighbour and (Bundesministerium für Wirtschaft und Klimaschutz, o. J.) the largest German medical technology companies by revenue are Siemens Helthineers, Fresenius Medical Care, Roche Diagnostics and B. Braun (Gilbert, 2021).

The subsequent research on the field made clear that advancements in big data have significant impacts on the medical technology industry in Austria. On one hand, big data has the potential to significantly improve patient care quality, optimise operations and accelerate research and innovations. On the other hand, it raised concerns over issues such as data privacy, transparency, and monopoly from big tech companies. Current data regulations, namely the EU's *GDPR*[1] and Austrian *Datenschutz-Anpassungsgesetz*[2] provide some guidelines but have several gaps regarding technology specificities and market regulation.

The goal of this research is to identify factors that are relevant for Austrian Medtech SMEs to effectively work with (Big) Data, to foster competitiveness in the EU area over the next decade. The research is motivated by the fact that, while small and medium enterprises (SMEs) are fundamental for the Austrian economy, the MedTech industry faces challenges in applying big data due to the abovementioned. The research aims to provide insights into how access to big data affects Austrian SMEs in the MedTech industry and how they can apply big data to drive better and more informed business decisions.

Given these premises, the group stated the first guiding question(s) as follows:

[1] https://gdpr-info.eu/

[2] https://www.parlament.gv.at/gegenstand/XXVI/I/68

- *(1) How does access to big data affect Austrian SMEs in the healthcare industry?*
- *(2) How can Austrian SMEs in the healthcare industry? apply Big Data to drive better and more informed business decisions by 2030?*

This question was created during the first workshop (December 2022), and the second part was added to insert an adequate framework.

At the beginning of the second workshop (January 2023), after background research, the guiding question was broken down into 3 parts. This number was not permitting easy and efficient communication of the goal of the research to the possible stakeholders. The different parts of it were therefore considered to be part of the framing and the research boundaries, while the GQ (guiding question) was grouped up subsequently (February) into just one comprehensive sentence:

- *Which competencies and access to Big Data do Austrian Medtech SMEs need to maintain their competitiveness?*

This version is the version that was sent by email to the stakeholders, asking for their feedback.

The following changes were done based on the feedback of the stakeholders and the subsequent team meetings and presented during the first Stakeholder Conference to show how we incorporated them and ask the experts to agree or not on that.
The changes revolved mainly around 3 concepts:
- competencies
- access
- maintenance

The first point, **competencies**, was too vague for some experts ("*Legal?, Scientific? organisational?...*"), while others claimed that could guide to a flattering of the discussion towards concepts related to education (*"competency, but my first thought would be that it mostly refers to the competency of people (experts) which will quickly turn the conversations towards education and how to provide SMEs an adequate job market*").

The second point, **access**, raised some critiques since data access is considered to be just one of the major barriers that SMEs face to working with Data. All of the different barriers mentioned by the expert will be incorporated into the System Boundaries.

For the last point, **maintenance**, the main issue was related to the supposed competitiveness and, particularly, the leading position of Austrian SMEs, which was not supported by the data.

Access and competencies were therefore put under the label of *factors* that *are relevant* for the SMEs. For what concerns the maintenance of competitiveness, the term was decided to be switched into the concept of fostering.

At the end of the first Stakeholder conference, the question was finalised into:

What specific factors are relevant for Austrian Medtech SMEs to effectively work with (Big) Data, to foster competitiveness in the EU Area over the next decade?

The choice to put the word "big" into brackets was done to underline the fact that the process will be focused on the use of data, even if the quantity itself might not consent to the attribute of *Big* Data. On the other hand, the area decided to cover is the *EU* one, since Austrian MedTechs might have peculiarity but they are anyhow moving in the EU regulatory, market, and opportunity framework.

To clarify the concepts mentioned in the GQ we define them as follows:

- SMEs: Small and Medium Enterprises (SMEs) in Austria are defined as companies with fewer than 250 employees and an annual turnover of up to €50 million, or a balance sheet total of up to €43 million. These companies constitute almost 99.6% of all national companies in 2020, with an added value of 134 billion euros (*SME DATA*, n.d.).
- Big Data: Big Data refers to data sets that are too large and complex to be processed by traditional data processing tools and require advanced analytical tools and technologies to extract insights and value (*What is Big Data*?, n.d).

2. System analysis: What do we know about the system

System Analysis

According to the System of Health Accounts (SHA), Austria spent a total of $45.4 billion in healthcare in 2017, which accounted for 10.4% of the country's GDP. Meanwhile, Austria's MedTech device market comprises around 550 companies, including 171 manufacturers and 383 distribution or service companies. Currently, Austria's medical manufacturers include a mix of large national companies with global operations such as MedEl (cochlear implants), Greiner Bio One (diagnostics) and Semperit (surgical and examination gloves), as well as medical Small to Medium size enterprises (SMEs), and the subsidiaries of multinational corporations such as GE Healthcare and Siemens Healthineers. Local production in 2017 reached approximately $2.3 billion with exports of just under $2.2 billion.

The majority of the medical devices are imported, with Germany being the largest supplier (33%), followed by the U.S. (15%). Other significant players in the market include Switzerland, South Korea, the Netherlands, China, and Japan. In 2017, the overall imports of medical equipment in Austria were valued at $2.27 billion with a continued upward trend projected. The market is driven by an ageing population, universal health insurance, rapid technological advancements, and poor lifestyle choices. However, the public healthcare payers' efforts to reduce spending and the EU's new, stricter regulations on certification and auditing requirements for medical devices pose significant challenges for the market.

The overall system model in which MedTech SMEs operate is influenced by various external agents, such as clients and patients but also varios data privacy and medtech regulation agents like the European Medical Device Regulation (EU MDR), local regulatory agencies such as Austrian Federal Office for Safety

in Health Care (BASG) that oversees the regulation of medical devices in Austria, and The Austrian Data Protection Authority together with the Austrian Chamber of Commerce ('WKO') that regularly issue guidance on privacy issues. SMEs that want to sell their medtech products or integrate work with big data must ensure that their products and services meet these regulations to avoid legal and financial penalties. Thus, these regulatory bodies have a significant impact on MedTech SMEs both in regards to the market expansion and the overall business growth. Failure to comply with the regulations may result in legal action, fines, loss of licence and significant loss of reputation.

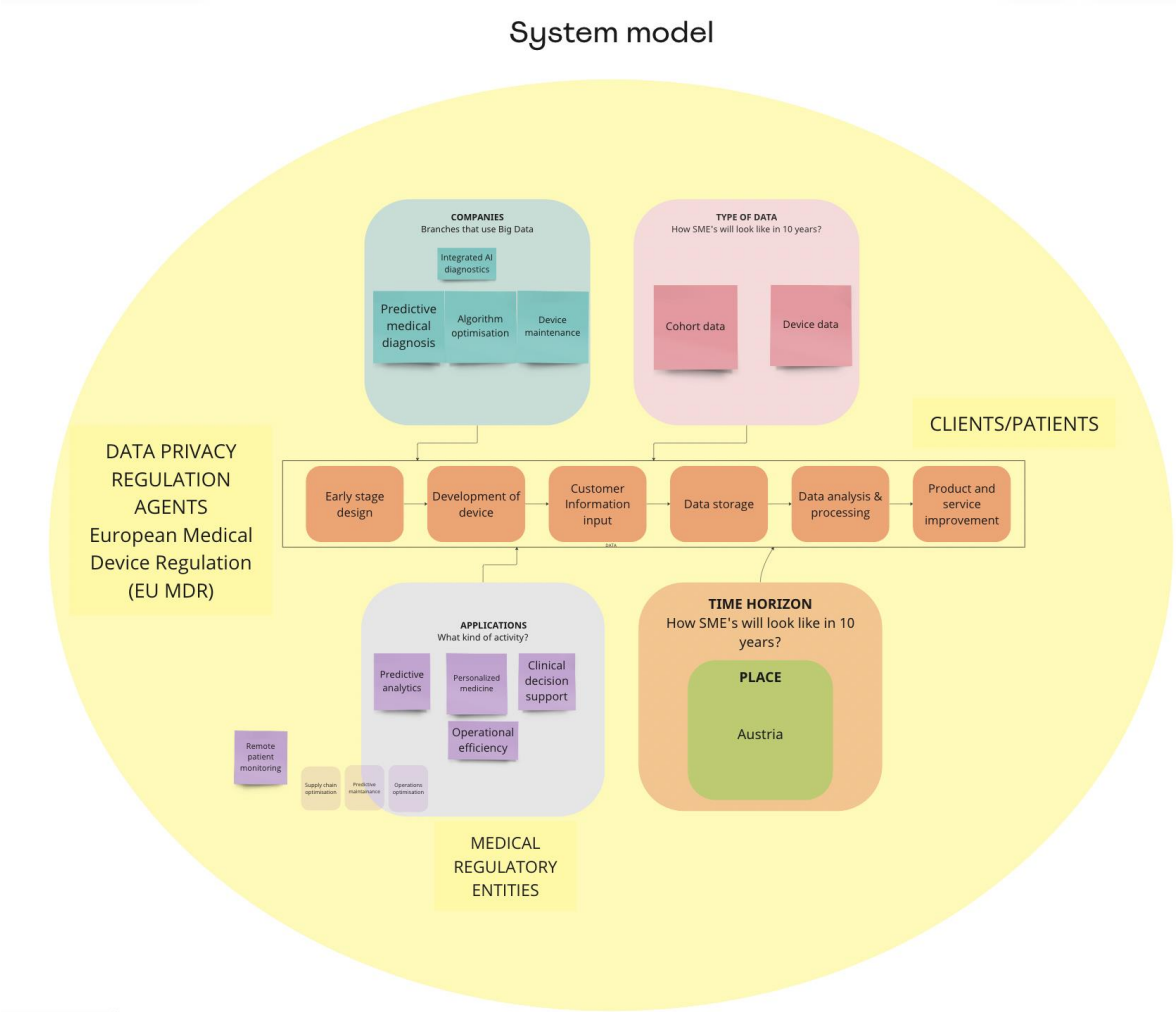
Moreover, regulatory bodies may impose strict, highly costly and highly time consuming certification and product approval procedures regarding product design, development, and overall approval, which may affect SMEs' ability to innovate and bring products to market quickly. Additionally, the classification of the medical device that the SME is selling determines the type of certification and registration that is required, and the Austrian classification process was updated in 2017 to become more rigorous. If the product is going to be sold in Austria and the seller or reseller has a presence in Austria, registration is also mandatory. Additional registration is required for testing labs and certifying bodies. In all other cases, registration is optional and can be done online at no cost (European Commision, n.d). Therefore, SMEs business growth and innovation is highly shaped by the regulatory and certification landscape of the market, which dictates the boundaries of the system and the level of access to patient data.

The system boundaries include the type of data that is limited to devise data and cohort data, the type of companies that focus on predictive medical diagnosis, algorithm optimization, device maintenance, integrated AI diagnostics, the time horizon of the next 10 years, the location in Austria, and the final system boundary is applications that extend to predictive analytics, personalised medicine, operational efficiency, and clinical decision support (See Graph 1).

The data flow process can be understood in the following way. In the early stage of product design, the MedTech SMEs gather requirements and define the product specifications based on customer information input. The R&D team then develops the product, and the data generated during this process is stored in a secure data storage system. Once the product is released, data is collected from the devices and analysed to improve product and service quality. The data is processed using big data analytics, and predictive algorithms are optimised to provide an accurate and timely medical diagnosis. During the product development process, MedTech SMEs must comply with data privacy regulations enforced by external agents such as EU MDR and medTech regulatory agents. They also consider clients'/patients' needs and expectations, ensuring that their data is secure and that they receive quality services. This way, the flow of data through different stages starts with customer information input, followed by product development, data storage, data analysis, and processing. The processed data is used to improve product and service quality and provide predictive analytics, personalised medicine, operational efficiency, and clinical decision support.

In summary, MedTech SMEs that utilise big data operate within a system model that is influenced by several external agents, including data privacy regulation agents (both local and international), medical

regulatory agents, and clients/patients. The system boundaries that limit data types, company types, time horizons, location, and applications dictate the flow of data through different stages. This flow enables SMEs to design and develop products that meet clients' needs, adhere to regulations, and deliver quality services. It is crucial to note that the compliance with data privacy regulations and standards is fundamental and highly influential on the business environment as regulatory bodies, such as the EU MDR, have a substantial impact on the operations of SMEs. They enforce strict rules and procedures that can hinder SMEs' innovation and product development. Failure to comply can lead to legal and financial repercussions, but also the overall reputational damage and financial penalties.



Graph 1. System Model of the MedTech SMEs and their use of Big Data.

The role of Big Data in Medical Device development and optimization

For what concerns the technical devices and their treatment, big data can offer opportunities for check-ins and improvements of the types of machinery, which can be used both for future development and for maintenance procedures. This would mean the industry to rethink the role of data science in product

design and lifecycle management since the use of integrated data allows an analysis process which is superior to the human one.

First of all, concerning the future development of technologies, the collection of big data and the use of data science can concern many steps of the development of technology such as:

- Identifying the medical need
- Identifying proper data variables
- Developing the right analytic models
- Designing analytic algorithm integrations
- Performing testing and verification
- Deploying beta versions
- Monitoring real-time results
- Maintaining and updating algorithms

This allows not a one-shot procedure but an ongoing process that has to be reviewed with the company to ensure that the product not just solves a problem but is also profitable and can be sold in the market.

In this sense, new applications are going in the direction of individualised eHealth and mHealth. And, if the patient and his data are central in the Big Data collection, they can be used for the development of the technology and to constantly monitor its work and possible failure to reduce the possible risk for the patient.

On the other hand, the maintenance procedure is already made more efficient by the collection and the process of big data. Otofacto, for example, does predictive maintenance for large medical services, reducing downtimes by predicting failure probabilities. They centrally collect the data of their devices, creating later a model to analyse recurrent patterns. Despite saving time and money for the company and non-interfering with the medical service with unpredicted damages, the collection of big data offered possibilities for the company's areas of:

- **Sales:** Manufacturers can better assess the use of the installed devices and draw up tailored offers for customers
- **Product development:** If specific parts are more vulnerable to faults, they can be optimised or replaced in development
- **Marketing:** The better you know a device's capacity utilisation, the more selectively you can advertise it.

The role of Big Data in Medical Image Processing

In the last two decades, medical imaging has undergone significant advancements through the use of cutting-edge techniques such as convolutional neural networks (CNN). These methods have demonstrated remarkable achievements in various medical imaging tasks, such as detecting microcalcifications in digital mammograms, by allowing the network to learn directly from the input image data (Zhang et al., 1994b).

The power of deep learning algorithms lies in their capacity to extract relevant information as high-level complex features by stacking multiple layers. The deeper the network goes, the more intricate the features become. Nonetheless, the potential of combining the big data analytics and deep learning algorithms together, especially in the context of medical imaging is still barely tapped (Tahmassebi et al., 2019b).

Applications

Big Data Analytics can significantly improve disease surveillance and detection. More specifically, unstructured medical image datasets can be analysed with greater efficiency to gain a better understanding of diseases and the necessary prevention and treatment methods, which can then lead to improved critical decision-making.

Medical images can reveal data about organs and the internal functioning of the body which is required to identify tumours, diabetic retinopathy, artery stenosis etc. Big Data Analytics platforms thus enabled quick diagnosis and prediction of treatment plans by storing, extracting, and analysing medical image data. This has been possible due to the efficient use of parallel programming and cloud computation, which have helped to overcome the challenges of processing massive amounts of data.

The field of medical image processing essentially involves extracting characteristics from images and identifying patterns in the extracted data. Different tools and frameworks, such as Hadoop, MapReduce, YARN, Spark, and Hive are utilised to accomplish this task. Machine learning and deep learning methods are also frequently employed for performing the necessary analytics. Additionally, genetic algorithms and association rule learning techniques are commonly utilised in this context (Bagga et al., 2021b).

Big Data Analytics

The future applications of Big Data include creating patient-specific personalised scanning protocols, scheduling scans, emergency reporting, radiologist decision support and virtual quality assurance for the radiologist.

Connection	Radiology Departments must have robust networks between the imaging modalities CT, MRI, Ultrasound and Radiography. This is because the patients' data generated from these medical scanners is transferred into the Hospital Information System (HIS), Radiology Information System (RIS), Picture Archiving and Communication System (PACS).
Cloud	The cloud stores radiological data in remote servers and connects them to the hospital computers for fast access, processing, and distribution of large data.
Cyber	Cyber relates to the computer processing power and memory required to process the query to obtain specific answers. Therefore, a complex question requires sizeable mainframe computers and higher processing power to achieve desired real-time results.
Content	This refers to the Digital Imaging and Communications in Medicine (DICOM) datasets. This system can be searched to obtain information relevant to a medical decision to help alter the patient line of management.
Community	Distribution of data to other healthcare organisations will allow providing a solution to a particular problem. For example, the sharing of radiology data could help regarding infectious diseases. The data would be in the form of chest radiographs during H1N1 influenza. Therefore, the analysis of Big Data may help in the diagnosis based on diagnostic imaging.
Customisation	The radiology data query should be customised using algorithms to facilitate a solution to a medical problem. The idea is to create the technology of clinical relevance and allow personalised healthcare.

Source: Open MedScience "From Pixels to Patterns: Big Data and AI Transforming Medical Imaging"

In addition to detecting disease states on organ function and anatomy, medical imaging provides important information. Additionally, it is used for artery stenosis detection, identifying tumours in lungs, organ delineation, aneurysm detection, spinal deformity diagnosis etc ("Integrating Big Data With Medical Imaging," 2019).

The role of Big Data in Hospital Management

To ensure the best in-house patient treatment in terms of quality, efficiency and rentability hospitals and clinics need not only to analyse patient data but also the data of their care delivery on an institutional level to improve their operations. Operations management comprises organisation and planning of the administrative and operational processes which involves:

- staff management (workflows and schedules but also training of staff)
- financial management (medical billing, healthcare claims,..)
- supply chain management (distribution and procurement of equipment such as pharmaceuticals but also masks or gloves and its proper disposal)
- coordination of all legal activities such as healthcare compliances.

Healthcare institutions therefore may also track staffing schedules, staff performance metrics, supply chain metrics, patient waiting times, insurance claims and medical referrals.

When looking at the UK and its current healthcare crisis we can understand that operational optimization is not only a matter of patient convenience but an essential influence factor of the patient's condition, for example, prolonged waiting times may even threaten the patient's life. While it is already proven that with big data-enabled analysis operational processes can be made more efficient by detecting patients' waiting time influencing factors to set according to changes, it is not yet widely disseminated. The main barriers for hospitals to use Big Data-powered analytics appear to be the lack of qualified personnel for Big Data analytics and data integration, as well as the cost of developing these analytics.

Other Applications of Big Data in MedTech

Other possible implementations of Big Data in the Healthcare sector regard their artificial intelligence and machine learning processes that include, among others, the implementation of predictive medicine. These possibilities, however, seem to the writers to be quite infrequently chosen by SMEs, but rather highly studied by the big players, that have resources not just in terms of money and time to allocate there, but also in terms of data that they already have to feed those algorithms.

- **Artificial intelligence (AI)** broadly refers to all analytical algorithms that iteratively learn from data, allowing computers to find hidden patterns and rules, even though they have not been pre-programmed in a way that would direct them how to look to learn the rules. It can imitate the cognitive functions of the human mind. The scope of the concept of artificial intelligence includes, among others, classic machine learning algorithms and new deep learning algorithms that can also be used to integrate and interpret complex biomedical data and healthcare data, in a way not provided with classic statistical methods.

- **Machine learning belongs** to the AI field and automates the construction of predictive models, focusing on the fact that the machine can learn from the data itself, change the learning algorithm and in this way can gain more new information from the processed data.

- **Deep learning** is based on multilayer neural networks – a series of algorithms that imitate the actions of the human brain and require a large amount of data to learn. It is particularly applicable to the analysis of medical images, whereas classical machine learning methods are more often used in the analysis of other medical data, such as the analysis of clinical electronic records.

3. Method

a. Description and design

Continuous societal changes, crises or transformations have led to new ways of generating, using and transferring knowledge in any field. Transdisciplinarity emerged from the need to integrate different epistemics of science and practice in complex systems(Scholz & Steiner, 2015).

In order to adapt to rapid changes in the midst of complex systems, we use transdisciplinarity as a methodology to understand the various factors impacting consistent and inconsistent scenarios. For instance, in challenges such as climate change, transition of energy systems, human and environmental health management and innovation trends, it is necessary to collaborate not only with actors from the same discipline but with different expertise that may have an active or passive influence in a given societal system.

Transdisciplinarity (TD) is a methodology of sustainable transitions, meaning that it is intended to analyse complex real-world problems in a collaborative and creative way while identifying status quo and potential development scenarios within a given system boundaries (Scholz & Steiner, 2015). In this vein, we planned 2 workshops to gather together scientists and practitioners to discuss the problem shaped as a guiding question. Therefore, the TD process was built as follows:

1. **Building of guiding question**

    a) **Identification of relevant societal problems:** The need to improve the competitiveness of SMEs in Austria, instilled the initiation of research about the potential factors.

    b) **Secondary research:** Gathering information about the potential field of applications within which the guiding question would be the pivotal reference to establish system boundaries.

    c) **Definition of system boundaries:** According to the literature review, we framed the guiding question into clustered types of actors needed to participate in the analysis and evaluation of the guiding question: Tech Industry, Medical Industry and Medical Academia.

2. **Stakeholders engagement:**

    a) **Contacts database:** After the system boundaries were defined, we gathered the contact details of potential representatives (scientists/practitioners) of each clustered type of actors. The contacts were collected from professional platforms and institutional websites. Simultaneously, the team could also approach representatives already known in the medical industry/academia.

b) **Engagement of stakeholders:** After the preliminary selection of up to 15 stakeholders, we introduced the main purpose of the research project by email, including:

i) **The proposed guiding question:** We asked them to provide us with feedback of the relevance and applicability of the guiding question according to their areas of expertise.

ii) **Request of potential evaluation criterias:** We requested a preliminary evaluation criterias (proposal of KPIs to measure the system). See section ii. The experts provided their proposed evaluation criterias and descriptions according to their background and experience in the MedTech industry.

3. **1st Stakeholder conference:** The 1st conference was dedicated to evaluate the validity of the guiding question. We facilitated the conversation among 6 experts using a brainstorming technique to discuss their arguments regarding their feedback in their response to the engagement emails. The discussion was led to be carried on within the limits of the system boundaries suggested by the research team. The main outcomes of the 1st conference were:

- Finalised guiding question.
- Validated evaluation criteria and description of the system.
- Construction of intuitive scenarios.

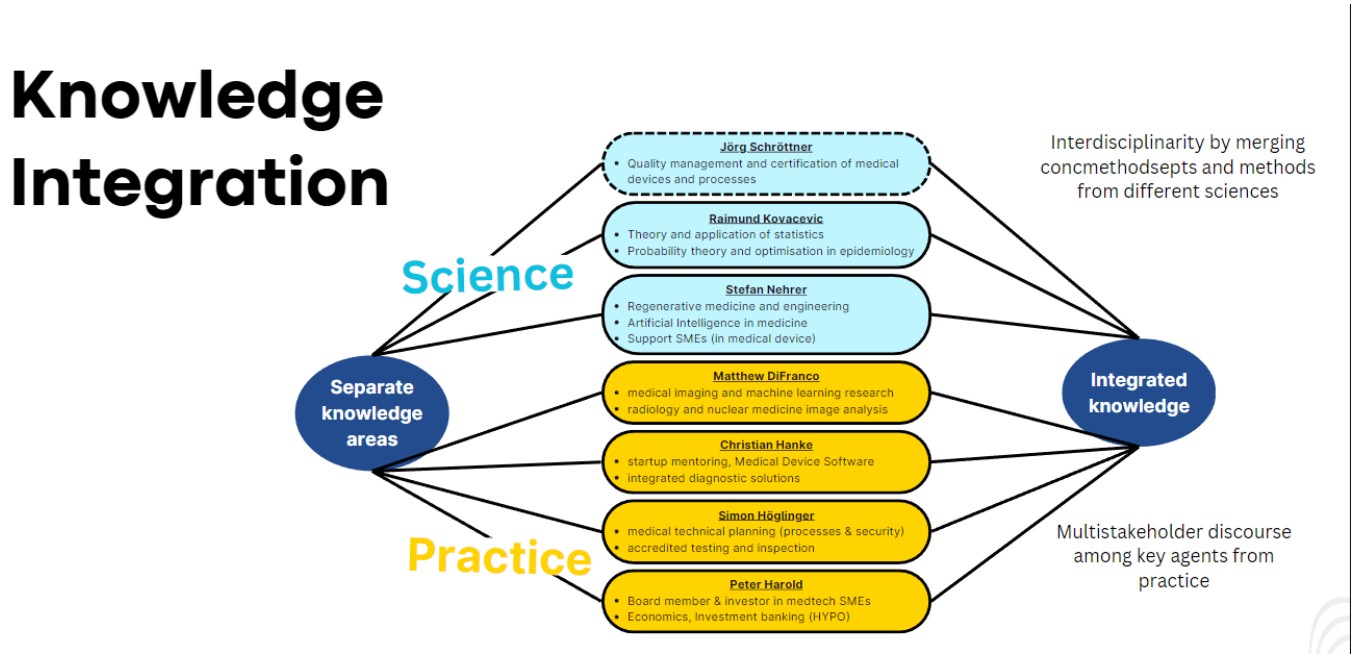
4. **2nd Stakeholder conference**

a) **Definition of impact factors:** After describing evaluation criteria and discussing the potential threat scenarios (worse and best case intuitive scenarios), we defined the potential impact factors as system variables that could affect the performance of the system in the future. Consequently, we defined the consistency scenarios matrix shown **in section 4. Results, point a.**

b) **Discussion of Impact factors, status quo and development scenarios:** During the 2nd stakeholder conference we used a brainstorming technique to collect information from the 6 experts about the 10 impact factors and 3 threat variables of the system. We confirmed the validity of **1 development scenario and 3 threat scenarios apart from the status quo scenario.**

b. Participants

As part of a transdisciplinarity we could work along with different kinds of participants during the whole process: Scientists, practitioners, students and assisting facilitators. The interaction among scientists and practitioners was crucial to have a complete integration of knowledge and build the threat scenarios.



Graph 2. Knowledge Integration.

1. **SCIENTISTS**

- **Raimund Kovacevic:** He works at the Department for Economy and Health at DUK (Danube University of Krems). His research mainly focuses on vaccination strategies during COVID-19, distributed optimal control model applied to COVID-19 pandemic, Poverty Traps and Disaster Insurance in a Bi-level Decision Framework.

- **Stefan Nehrer:** Dean - Faculty of Health and Medicine at DUK. Previous projects include Artificial intelligence in orthopaedic radiography analysis, Tribology Intelligence - Customised Tribology for Industrial Innovations. One of his papers is titled "Deep Learning for Fully Automated Radiographic Measurements of the Pelvis and Hip".

2. **PRACTITIONERS**

- **Peter Harold:** Former CEO – HYPO NOE Gruppe Bank AG. Board member & investor in MedTech SMEs. He has 20 years of board position experience; president of cultural heritage society; supporting university activities; co-owner of a medical centre in Bulgaria and has previous experience of banking in Bulgaria.

- **Simon Höglinger:** He completed a Bachelor's and Master's degree in medical technology between 2011 and 2016. He then did a research project in the US on the field of medicine and medical technology. Since 2017, he has been employed as a project manager in the field of medical technology planning and laboratory planning for healthcare facilities and medical research facilities.

- **Christian Hanke:** He has 25 years of experience in software and healthcare, both in startup and big corporate environments. Now he is doing startup mentoring, specialising in topics: Medtech, Medical Device Software, Artificial Intelligence, Deep learning, Annotation. Previously he was a Sr Director Informatics EMEA, Integrated Diagnostic Solutions at BD (one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care.

- **Matthew DiFranco:** Chief Scientific Officer and Head of Clinical Research at ImageBiopsy Lab. He works in the field of AI and radiology, software for medical devices and medical imaging which relies on big data.

3. FACILITATORS

- **Liliya Satalkina:** She is a post-doc researcher at the Department for Knowledge and Communication Management at the Danube University Krems. She has a PhD degree in economics, in a field of investment and innovation activity of enterprises. Liliya was awarded with a Research Scholarship of the Scholarship Foundation of the Republic of Austria for Postdocs (OeAD).

- **Roland Scholz:** Chief senior scientists, ETH Zurich background, psychology and game theory background, 1978 - epileptic therapy and how the data is recorded from the patients, big data on vulnerabilities of german healthcare system; highlighted that we are participating in the new research practice that allows students to learn through transdisciplinary process.

4. STUDENTS:

- **Kamilya Issaliyeva:** She graduated as a University Honors Scholar with a B.A. in Political Science and Film & New Media from NYU Abu Dhabi. She is skilled in Communications, Multimedia production, Design Thinking, and Stakeholder Analysis. Kamilya is excited to contribute to system resilience and make a lasting positive impact on projects that prioritise community well-being and bring forward innovative solutions.

- **Chiara Miozzo:** Coming from Italy, Chiarahas a BA in Economics and Management of Art and a Minor in Computer and Data Science. She is an interdisciplinary professional who founded an NGO aiming to connect local cultural realities with children and families. She is interested in the digitalisation of community-centred processes and their policies.

- **Ngan Pham:** Ngan is a multidisciplinary professional with a passion for innovative & responsible technology. From Vietnam, she has worked in the cross-section of education, sustainability, and user-centred design with organisations from 4 continents. Currently working in mHealth, Ngan is committed to learning about Austrian health tech and creating a positive impact through this project.

- **Franziska Schranz:** Franziska is an innovation manager from Austria with 3 years of professional experience. She holds a Bachelor's degree in Innovation, Engineering and Management. She is highly motivated to work together with academia and practitioners for a resilient and innovative Europe.

- **Diana Ruiz:** Ecuadorian Industrial Engineer. Her passion for instilling motivation and perdurable engagement in her community has shaped her as an integrative leader, effecting meaningful changes in her sphere. She looks forward to connecting large and multi-sectoral teams advocating for strategic cooperation at a big social scale. She aims to create a high-committed society based in inclusive and efficient structures in more sustainable environments while propelling transdisciplinary collaboration.

c. Variables

i. Impact variable of status quo (and status quo)

An impact factor (IF) is a system variable or a variable that serves as (case or system) descriptor (ii = 1, … ,II) of a real-world case (Takam & Scholz, 2021). In this case we used the impact factors we could identify during the formulation of the intuitive scenarios in order to build the status quo.

The low and high characteristics are based on desk research and were discussed with the experts in the second stakeholder conference. These variables are used to describe the characteristics of the system, and the low and high values indicate how these descriptors could develop positively or negatively over a ten-year period. The first version of the impact variables are the following:

Table 1. Proposed impact factors (first version)

IMPACT FACTORS	LEVELS	
	High	**Low**
D1 - Data Accessibility	Data registries that are reliable and publicly available, and affordable for small and medium enterprises.	Data access remains the same or less than the status quo.
D2 - MDR Regulations	Moderate level of regulations that enable SMEs to comply with limited resources and innovate while ensuring patient safety.	MDR regulations remain the status quo.
D3 - Societal Trust in The System	> 80% of Austrian citizens trust in the system and allow their data in an anonymized form to be used to innovate processes, products and services.	< 20 % of Austrian citizens trust in the system and allow their data to be used to innovate processes, products and services.
D4 - Educational Opportunities	Increase of university programmes in MedTEch.	Reduction of university programmes for MedTech.
D5 - Research and Innovation Grants	Reduction in funding complexity, Transparency and consistency for manufacturers.	Funding process is complex and uncertain for manufacturers.
D6 - Intra and Cross-sector collaboration	Building of stakeholder ecosystems. Incentivization for collaboration of stakeholders. Building a branch overarching data repository. No conflicting interests. The number and nature of joint initiatives, partnerships, or collaborations, and the effectiveness of these collaborations in achieving shared goals is growing.	Status quo remains as it is. No ecosystem is built. No incentives for collaboration. There is a high frequency of conflicts or disputes among stakeholders, and the extent to which these conflicts impede progress or innovation. There is an increased level of conflicts or disputes among stakeholders, and the extent to which these conflicts impede progress or innovation.
D7 - Innovation Costs	Reduction of costs associated with Integration costs, maintenance,	High costs to fulfil regulatory requirements and high costs

	cloud keep-up, servers, and purchasing costs of data.	associated with Integration costs, maintenance, cloud keep-up, servers, and purchasing costs of data.
D8 - Public Awareness of Data Benefits	Increase of positive media campaigns regarding sharing data, which results in increased trust from the population in use of their private data for anonymized data libraries.	Public Awareness remains the status quo. There is an increase in negative media regarding GDPR.
D9 - Data Standardization	>70% of Healthcare Providers follow the same set of rules or guidelines to standardise the data that they collect, store and share with the data library.	<30% of Healthcare Providers follow the same set of rules or guidelines to standardise the data that they collect, store and share with the data library.
D10 - Data Libraries	The EU has its own anonymized public healthcare data bank with standardised data.	The EU does not have its own anonymized public healthcare data bank with standardised data and relies on an external data library from the US or other markets.

The status quo was defined as the combination of impact factors affecting the current situation of big data influencing the MedTech sector. The status quo scenario was explained as the system analysis **in section 2.**

ii. Evaluation criteria

The evaluation criteria was designed from the feedback of the experts and the discussion during the 1st stakeholder conference.

The construction of the evaluation criteria is the most challenging, difficult, and time expensive as the construction of impact factors. The evaluation criteria can be seen as the measurements by which the system is assessed to be successful, in this case, the variables that SMEs would need to take into account in order to foster their competitiveness in the context of big data. See the final version of the evaluation criteria in section **4. Results, part a.**

iii. Threat variables

In a complex scenario, threat variables refer to factors or conditions that have the potential to cause harm, damage, or disruption to the system or environment being analysed. Threat variables can come from a wide range of sources, including natural disasters, technological failures, social unrest, economic downturns, or political instability.

The identification and analysis of threat variables is an important aspect of risk management and preparedness planning in complex scenarios. By understanding the potential threats to a system or environment, stakeholders can develop strategies and measures to mitigate or prevent the negative impacts of those threats.

In a complex scenario, the identification of threat variables can be challenging due to the many interconnections and interdependencies between different parts of the system. The analysis of threat variables must take into account the complex and dynamic nature of the scenario, and consider the potential cascading effects that a threat in one area of the system may have on other areas. The threat variables were the main input to build the threat scenarios in the next section of results. Such scenarios were analysed in contrast with the development scenarios defined by the stakeholders in the 2nd conference.

4. Results

a. Evaluation Criteria

The evaluation criteria constructed and discussed together with the experts in the pre phase and during the 1st Stakeholder Conference are listed below in Table 1. Those criterias allow us to assess the overall performance of the Medical Technology SMEs in Austria which provide services in predictive medical diagnostics and integrated AI diagnostics. While *u1* to *u5* follow a bottom up approach and describe company specific metrics for success like market share of that specific company, innovation capacity, the efficiency of their internal processes and retention of expertise , *u6* describes the system environment. The latter includes the amount of research grants available for this specific industry, total of innovative products patented by Med Tech SMEs and their relative contribution to Austrian GDP.

Not all evaluation criteria have the same importance for the system's success therefore they were weighted in a second step (see chapter E. Weighting of the evaluation criteria).

Table 2. Evaluation criteria and their definition.

	Evaluation criteria (uj)	Short definition	Metrics
u1	Profitability		-Market share of the Patient and Health Market.
u2	Product Innovation	Opportunities and activities to innovate.	-R&D spending -Agility & Adaptability -Benefit of the patient -Assessing needs -Customer Satisfaction -Number of Patents.
u3	Social Responsibility	Proven safety and effectiveness of the product. This evidence is often required for regulatory purposes, but is also extremely important for winning customers.	-Data security and cybersecurity -Level of Clinical/Medical Evidence.
u4	Operational Improvement	Efficiency of internal processes	-Quality of the product -Scalability -Interoperability (ability of the product to work in diverse operating environments)
u5	Expertise	Availability of crucial legal and technical expertise	-Partnership and collaboration -Talent acquisition and retention -Technical and legal expertise (especially in the field of regulatory affairs in the interaction of QMS, RM and PMS).
u6	System/Industry Environment	Overall performance and systemic support of the Medical Technology branch.	-Amounts and Availability of Research Grants that are assigned to that industry/branch -number of innovative products -contribution to GDP of that industry/branch.

b. System variables and Impact matrix

In the discussion with the experts, it was emphasised that for many variables the current state is suboptimal and therefore "the status quo remains" was used as a low, negative expression of this variable.

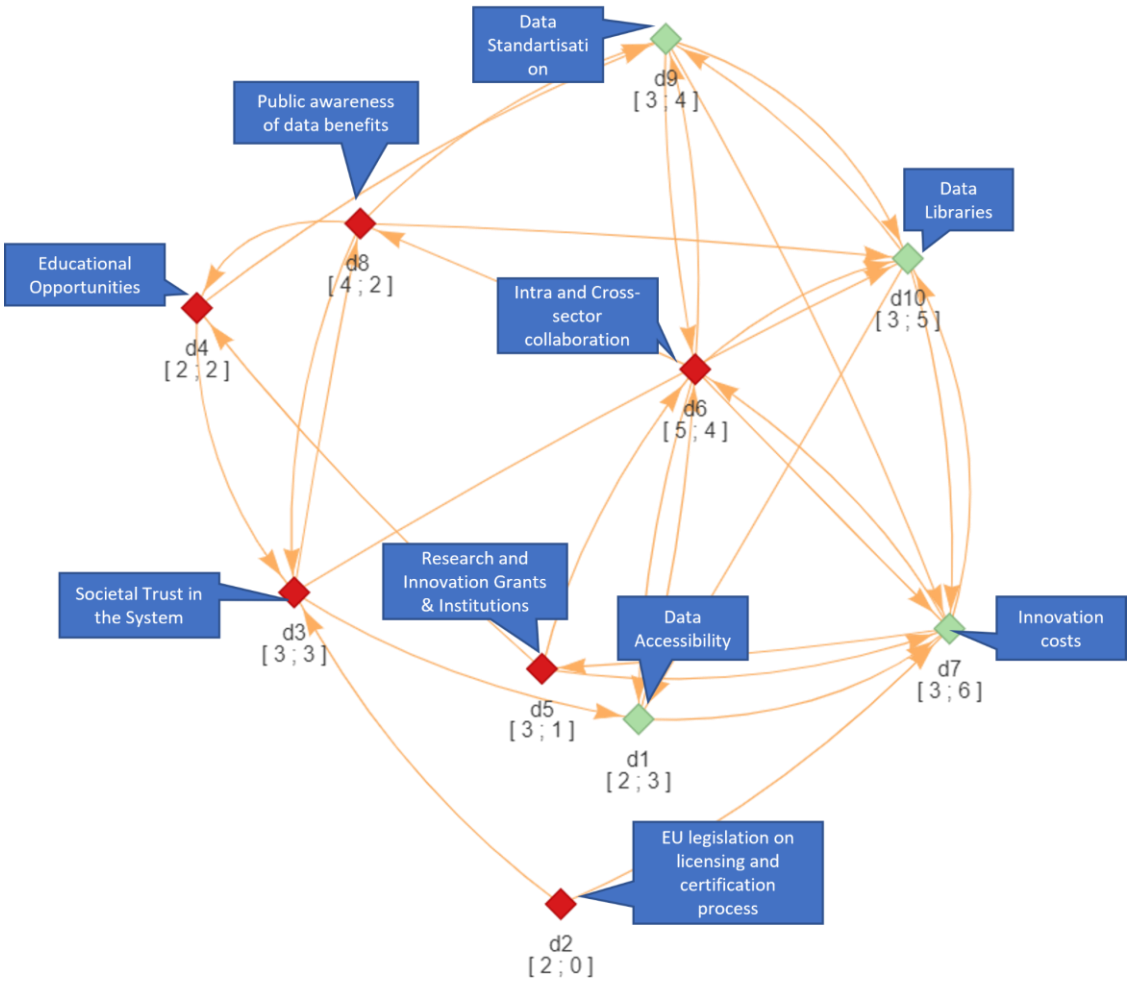
Table 3. Impact variables and their positive and negative manifestation (final version).

No.	System variables		Possible characteristics 2033	
	Label	Description	Low	High
d1	Data Accessibility	Big data pools with relevant training data (anonymized cleaned and/or aggregated cohort data), which is constantly growing and held up to date are accessible (the data can be retrieved easily and cheaply).	Same or less than status quo.	Data registries that are reliable and publicly available, and affordable for small and medium enterprises.
d2	European legislation on licensing and certification process	To which extent medical device regulations (MDR) are not an obstacle to innovate and under which SMEs are capable of complying with regulations and innovating.	MDR regulations remain as the status quo.	Moderate level of regulations that enable SMEs to comply with limited resources and innovate while ensuring patient safety.
d3	Societal Trust in the System	Describes whether there is a strong level of public trust towards the health systems to collect, process, and store their personal health data in an ethical and secure way. If they see centralised data collection as a benefit for all and consequently, their willingness to “donate” data towards the development of cooperative open data centres.	20 % of Austrian citizens trust in the system and allow their data to be used to innovate processes, products and services.	More than 80% of Austrian citizens trust in the system and allow their data in an anonymised form to be used to innovate processes, products and services.
d4	Educational Opportunities	Amount of study programs offered by universities and universities of applied sciences that cover the skill set to work in MedTech like Mathematics, Statistics, Informatics, Data and Computer engineering. Schools for technical engineering for medtech.	Reduction of university programmes for MedTech.	Increase of university programmes in MedTEch.

d5	Research and Innovation Grants & Institutions	Scope (in € million) of funding options available to medical technology SMEs for carrying out research and innovation measures.	Complex processes of funding and uncertainty for manufacturers.	Reduction of funding complexity, Transparency and consistency for manufacturers.
d6	Intra and Cross-sector collaboration	The variable looks at the level of collaboration within and across the branches of the medical technology industry and other relevant stakeholders across the supply chain. At the moment every stakeholder has different and conflicting interests and incentives in sharing data with other stakeholders.	Status quo remains. No ecosystem is built. No incentives for collaboration.	Building of stakeholder ecosystems. Incentivization for collaboration of stakeholders. Building a branch overarching data repository. No conflicting interests.
d7	Innovation costs	Capacity to innovate regardless of regulations.	High costs to fulfil regulatory requirements and high costs associated with Integration costs, maintenance, cloud keep-up, servers, and purchasing costs of data.	Reduction of costs associated with Integration costs, maintenance, cloud keep-up, servers, and purchasing costs of data.
d8	Public awareness of data benefits	Public awareness of data benefits refers to the level of knowledge and understanding among individuals and communities about the value and potential uses of data. This includes awareness of the benefits of data collection, analysis, and sharing, as well as the potential risks and challenges associated with data use.	Remains of status quo. Increase of negative media regarding GDPR.	Increase of positive media campaigns regarding sharing data, which results in data donations.
d9	Data Standardization	The process of transforming data into a common format or structure so that it can be easily compared, analysed, and interpreted. This involves converting data from its original format or	<30% of Healthcare Providers follow the same set of rules or guidelines to standardise the data	>70% of Healthcare Providers follow the same set of rules or guidelines to standardise the data

		representation to a standardised format that follows a specific set of rules or guidelines.	that they collect, store and share with the data library.	that they collect, store and share with the data library.
d10	Data Libraries	A publicly available collection of healthcare-related data anonymized, standardised and well structured. To provide researchers, healthcare professionals, SMEs and policymakers with a valuable resource for analysing healthcare trends, evaluating treatments and interventions, and identifying areas where improvements in healthcare delivery are needed.	The EU does not have its own anonymized public healthcare data bank with standardised data and relies on external data libraries from the US or other markets.	The EU has its own anonymized public healthcare data bank with standardised data.

The system graph below shows the interaction of the system variables from **Table 2** . While the regulative framework (*d2*) can not be directly influenced by the Med Tech branch it strongly influences the costs to innovate (*d7*) since medical devices have to follow a complex technical documentation and costly and lengthy certification process in order to comply with EUs MDR. According to the experts, companies are moving to China and the United States because they cannot comply with MDR regulations, which require clinical proof before products can be sold, thus hindering local market's innovation. Advanced therapy medicinal products (ATMP) regulations further complicate innovation efforts. Very few companies obtain the required certifications, and conducting the required studies is too expensive because the product itself is often sold at a low price, making the amortisation of certification efforts too high. However, on the other side do the strict regulations and safety measures strengthen the trust of Austrian citizens in the system (*d3*) to provide safe diagnostic and treatment devices and measures.



Graph 3. System graph based on the influencing factors of the data driven SME system in the Medical Technology branch.

Collaborative projects and efforts *(6)* within the Med Tech branch are central to the system. First, societies' perceptions (*d3, d8*) regarding the use of their health data can be positively influenced by joint lobbying and communication campaigns. Experts describe that there are currently very few activities in the area of lobbying. Second, development and innovation cost (*d7*) can be reduced by joint R&D activities and shared expert knowledge and skills. Finally, collaborative developed data commons and data collection built the base of structured available and easily accessible data (*d1, d9, d10*). Austria is lacking cross-provincial and cross-regional standardisation of the health system and procedures.

All data related variables, Data Standardisation (*d9*), Data Libraries (*d10*) and Data Accessibility (*d1*), are passive. Standardisation and Libraries refer to local Austrian/ European cleaned and structured data pools,

which are according to experts in Austria non-existent and in the EU only very limited. As already mentioned above the main issue is the non uniform collection of health data, but also the centralised storage of health data. The omission of the latter was especially noticeable during the COVID-19 pandemic, when no representative estimations of trends could be based on Austrian patient data. The example of ELGA, an Austrian electronic health record data bank, highlights the impact of society's perception of data privacy and security on building centralised health data banks. ELGAs dissemination since its introduction was rather low since patients have the opportunity to opt out of centralising their data and it received major push back from the public.

As discussed in the first stakeholder conference do the experts agree that Austrians are rather cautious with sharing their personal data. For example, it was mentioned that nobody in the political arena wants to touch the topic of open source anonymised health data because they are interested in the reelection. However, this would be very helpful for randomised trials, currently they are based on the result on a very specific collection of data and do not represent the real world. The lack of Austrian data libraries (*d10*) is, among other things, the result of the lack of awareness (*d8*)of the benefits that such a library would bring to the population. One expert emphasised that the Austrian healthcare system is one of the most expensive in Europe and the cost of maintaining it will be enormous in the face of an ageing population. Austria therefore relies heavily on innovation (*d7*) and process optimization, both of which require sufficient data. However, access(*d1*) to data can also be obtained by buying training data from other countries like the US, which has a pioneering role in this field.

Another resource for innovation is professional and qualified analysts who work with data. In Austria, the education (*d4*) in medical technology, which includes medical IT, is good, and there are also many biotechnology courses at universities. One observation made by the experts was that the education component is one of the main reasons for SMEs to locate in a certain area, SMEs come because of the skilled workforce.

c. Consistent Development Scenario 2033

Overall, the following scenario is described by high levels of data accessibility, cross sector collaboration and decrease in the innovation costs. Nonetheless, some major barriers prevail. There is still no single reliable anonymised data library developed and owned by the EU, while the level of MDR regulations remain as high as it is during the status quo. As a result, the amount of public funding that goes into educational opportunities and innovation grants start to decrease; while the public remains unaware about the overall benefits of having shared anonymised data bases and their overall trust in the system remains low. Furthermore, a combination of high level of MDR regulations, low research funding, low educational opportunities and public trust, perpetuates the monopoly of big medtech companies in talent acquisition and large-scale innovation outputs.

Scenarios	IF1	IF2	IF3	IF4	IF5	IF6	IF7	IF8	IF9	IF10	Konsistenzwerte K(S.)
S2	1	0	0	0	0	1	1	0	0	0	75

High Values: Data Accessibility, Intra and Cross-sector Collaboration, Innovation Costs.

Low Values: Educational Opportunities, Research and Innovation Grants, Data Standardization and Data Libraries, MDR regulations, Societal Trust in the System and Public Awareness of Data Benefits.

Scenario Description:

Under the following scenario, all stakeholders have open access to reliable external big data pools with relevant training data (anonymized, cleaned and/or aggregated cohort data), which is constantly growing and held up to date. The data is easily accessible (the data can be retrieved easily and cheaply) for all the relevant stakeholders, including the small and medium enterprises in the Medtech industry. Therefore, the training data is available to be processed and applied towards the development of MedTech innovations in products and services. This high rate of data accessibility, however, happens despite the availability of EU-owned data libraries. This means that although the overall level of access to data is high, the majority of stakeholders are still reliant on external foreign market databases. Not only does the market lack internal EU-owned data libraries, but the market is also described by the low level of data standardisation, which results in <30% of Healthcare Providers following the same set of rules or guidelines to standardise the data that they collect and store.

Nonetheless, there is an improvement in the number of intra and cross-sector collaborations among the associated stakeholders. Under the following scenario, the stakeholder ecosystem is being built in a more interconnected network with high and apparent incentivization for collaboration, which can later result in the joint efforts to build a branch overarching data repository. The number and nature of joint initiatives, partnerships, or collaborations, and the effectiveness of these collaborations in achieving shared goals is growing, and there is no apparent conflict of interest that prevents joint cross-industry efforts.

Another important factor associated with the following scenario is a significant reduction in innovation costs. More specifically, there is a reduction of costs associated with integration costs, maintenance, cloud keep-up, servers, and purchasing costs of data. As a result, the companies have more resources to invest in data processing infrastructure and innovation. At the same time, however, the level of MDR regulations remains as high as they are during the status quo, which can counterbalance the speed to progress, given that the current levels of MDR regulations are often seen as barriers to innovation.

This scenario, however, is also defined by low levels of such important factors like Educational Opportunities and Research and Innovation Grants. This means that under the following scenario, there might be reduction in university programs and funds that are available for research in MedTech related topics. Funding opportunities can be associated with high levels of uncertainty and complex processes for the manufacturers. The combination of these factors can discourage youth to pursue a career in MedTech, which will result in the shortage of experts and professionals to drive innovation and even maintain the quality of products and services in the industry.

Last but not least, public awareness of the data benefits remains as it is during the status quo. This means that a large portion of the population remains unaware or misinformed about the social and industry benefits of anonymised data collection, analysis, and sharing, as well as the potential risks and challenges associated with data use. As a result, the following scenario is also described by the low values of societal trust in the system. This means that less than 20% of Austrian citizens trust in the system and allow their data to be used to innovate MedTech processes, products and services.

d. Threat scenarios:

d.1 Threat scenario 1: Geopolitical Turmoil 2033

As we discussed, a key factor in the data and medical field is dependent on the socio-political system. A disruption in geopolitics can pose a significant threat to the big data field and MedTech SMEs, as it can cause a disruption in the global supply chain of electronic components necessary for processing big data. The shortage of software chips caused by the conflict between Taiwan and China, for example, can lead to increased costs, delayed projects, data security risks, and innovation stagnation for Medtech SMEs globally and in Austria.

In the current geopolitical climate, tensions between China and Taiwan remain high due to long standing political and economic disputes. Given this context, there is a possibility that a military conflict between China and Taiwan could arise in the future, potentially leading to a disruption in the global supply chain of electronic components, particularly software chips that are developed in Taiwan. The increasing dependence on electronic components for processing big data, coupled with the growing importance of big data in the Medtech industry, means that any such disruption could have severe consequences for Medtech SMEs in Austria. Furthermore, tensions between these 2 global players can spill over to their allies and the international community, leading to a world of deglobalization and disrupted supply chain of other key resources and services for the medical technologies, including device components, joint research projects, healthcare services.

Table 4. Threat variables on the threat scenario 1.

Threat Variable	Low Threat Level (1)	High Threat Level (2)	Assumptions for Geopolitical Turmoil 2033 and its impact on Big Data in Austrian

			Medtech SMEs
Access to software chips	The supply chain for software chips remains stable	The supply chain for software chips is disrupted due to geopolitical turmoil	Possible war or conflict between Taiwan and China, leading to disruption in the supply chain of software chips
Data access and security	Data access and security protocols remain unaffected	Increased cyberattacks and data breaches due to geopolitical turmoil	Increased cyberattacks and hacking attempts due to geopolitical instability, compromising data access and security
Talent retention and recruitment	Stable supply of skilled personnel with relevant expertise	Brain drain due to geopolitical turmoil	Geopolitical instability leads to a decrease in talent retention and recruitment, resulting in a shortage of skilled personnel with relevant expertise
Government policies and regulations	Stable regulatory environment with supportive government policies	Changes in government policies and regulations due to geopolitical turmoil	Geopolitical instability leads to changes in government policies and regulations, which may not be supportive of innovation and competitiveness
International collaboration and partnerships	International collaboration and partnerships remain unaffected	Breakdowns in international collaboration and partnerships due to geopolitical turmoil	Geopolitical instability leads to a breakdown in international collaboration and partnerships, hindering knowledge-sharing and cooperation, and slowing down innovation and progress.

d.2 : Data Monopolization and Data Oligarchies 2033

Another threat scenario is data monopolisation. As the industry becomes more data-driven, the demand for access to big data increases, which can lead to a concentration of data ownership and control in the hands of a few large corporations. The high regulatory and certification barriers for innovation and business development can limit the entry of new players into the market, allowing the existing corporations to establish data monopolies. Additionally, the lack of effective regulations to prevent data monopolisation and promote free market competition can enable the large corporations to manipulate the market in their favour.

As a result, in 2033, the Austrian MedTech industry falls into data monopolisation and data oligarchies due to the lack of free market competition caused by high regulatory and certification barriers to innovation and business development for SMEs. A few large corporations from abroad gain complete control over the collection, processing, and dissemination of all the big data applicable for the MedTech industry. These corporations have monopolised the data banks and can decide on unregulated price points for accessing their data banks. Moreover, the large corporations can manipulate the data to favour their interests, further limiting the SMEs' ability to compete. This scenario can result in a significant power imbalance

between the few large corporations and the MedTech SMEs, ultimately hindering the industry's growth and innovation.

Table 5. Threat variables for the Data Monopolization and Data Oligarchies 2033 Scenario.

Threat Variables	Low Threat Level (1)	High Threat Level (2)	Assumptions
Legal and Regulatory Framework	There is a transparent and competitive legal and regulatory framework that enables fair market competition for data ownership and usage.	The legal and regulatory framework is opaque, non-transparent and favours big corporations, creating barriers to entry for SMEs.	The legal and regulatory framework in Austria is currently in favour of big corporations, and there is no significant effort being made towards creating a transparent and competitive legal and regulatory framework.
Access to Data	SMEs have equal access to data banks with big corporations, and there is no discrimination in terms of price, quality, or quantity.	SMEs have limited access to data banks with big corporations, and there is significant discrimination in terms of price, quality, or quantity.	Due to lack of innovation and business development in SMEs, they have limited access to data banks with big corporations who have monopolised the market.
Innovation and Business Development	SMEs are supported and encouraged in terms of innovation and business development, which allows them to compete with big corporations.	SMEs face significant barriers to innovation and business development, leading to their inability to compete with big corporations.	The current market conditions do not favour SMEs and there is no significant effort being made towards creating a supportive environment for their innovation and business development.
Industry Concentration	The MedTech industry is highly fragmented, with no dominant players, which fosters a competitive market environment.	The MedTech industry is highly concentrated, with a few dominant players, leading to limited market competition.	Due to the lack of innovation and business development in SMEs, the MedTech industry is highly concentrated with big corporations having a significant market share.
Data Security and Privacy	Data security and privacy regulations are strictly enforced, ensuring that all data is collected, processed and disseminated in a secure and ethical manner.	Data security and privacy regulations are weakly enforced, leading to the misuse of data, breaches, and potential harm to individuals.	Due to the lack of innovation and business development in SMEs, the responsibility of data collection, processing and dissemination lies with big corporations who may not have the necessary measures in place to ensure data security and privacy.

d.3: Mass Protests against the use of Big Data 2033

Public trust and attitude is another key variable in both the socio-political system and the data and medical industry. In the last decade, several major data outbreaches, data malicious manipulations, unethical data-based profiling scandals, to name a few, have undermined public trust in both the states and companies' handling of data.

Thus, a possible threat scenario is mass Protests against the use of Big Data 2033, where a malicious cyberattack on data libraries used by a public data bank results in significant reputational damage. As a result, there is a widespread social outcry against the use of big data by corporations and governments, with concerns over privacy and the potential for misuse of data. This causes disruption in anonymized patient data processing and leads to a media scandal, which in turn causes a loss of public trust in these institutions. As a result, less than 20% of Austrian citizens trust in the system and are willing to allow their data to be used to innovate processes, products, and services. This leads to an industry-wide disruption in the data pipeline and medical system in Austria.

Table 5. Threat Variables for the Threat Scenario of Mass Protests against the use of Big Data 2033.

Threat Variable	Low Threat Level (1)	High Threat Level (2)	Assumptions
Public Trust	Citizens still trust the regulatory institutions, SMEs, and public data banks to handle their data responsibly.	Less than 50% of citizens trust the regulatory institutions, SMEs, and public data banks to handle their data responsibly.	Big MedTech companies are still able to access enough big data from foreign sources using their capital advantages, but it is not the case for SMEs. This in turn widens the power imbalance and innovation gaps between big-tech and SMEs.
Government Regulation	Government is able to regulate the use of big data in a way that balances privacy concerns with the need for innovation.	Government is unable to regulate the use of big data effectively, leading to excessive restrictions on the use of big data for innovation.	Austrian medtech SMEs are forced to rely on alternative sources of data or face legal repercussions for using big data in their products and services.
Cybersecurity	Robust cybersecurity measures are in place to prevent malicious cyberattacks on data libraries.	Cybersecurity measures are inadequate, resulting in frequent cyberattacks on data libraries.	Austrian medtech SMEs struggle to access reliable and secure sources of big data due to frequent cyberattacks and potential reputational damage.
Media Coverage	Positive media coverage and public opinion about the use of big data in healthcare innovation.	Negative media coverage and public opinion about the use of big data in healthcare innovation.	Austrian medtech SMEs struggle to gain public trust and access to big data, leading to difficulty in innovating and developing their products and services.

Data Security and Privacy	Data security and privacy regulations are strictly enforced, ensuring that all data is collected, processed and disseminated in a secure and ethical manner.	Data security and privacy regulations are weakly enforced, leading to the misuse of data, breaches, and potential harm to individuals.	Due to the lack of innovation and business development in SMEs, the responsibility of data collection, processing and dissemination lies with big corporations who may not have the necessary measures in place to ensure data security and privacy.

E. Weighting of the evaluation criteria

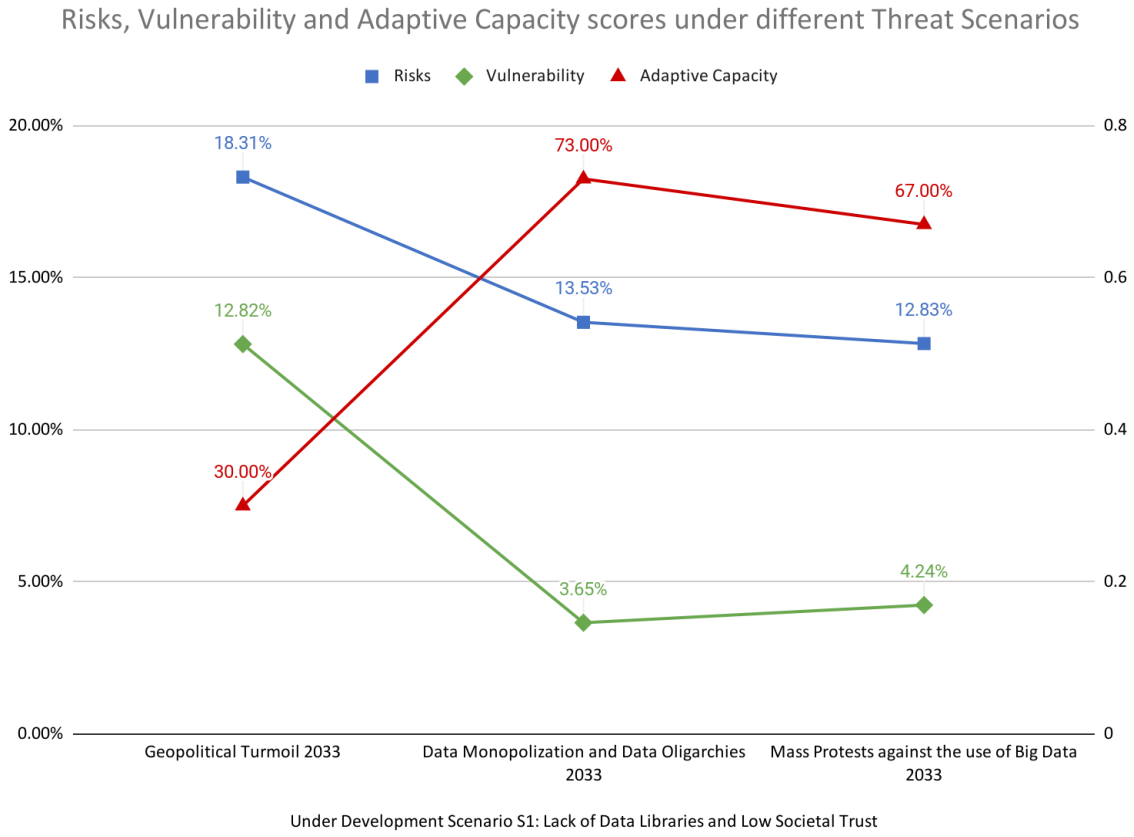
Due to time and resource constraints of the project, the following table presents weighting of the evaluation criteria, based on our team's understanding after the inputs from experts and literary research.

Table 6. VS05 ratings on development scenarios and their combinations to threat scenarios on a "0 to 200 scale."

			Status quo, development scenarios, and development scenarios under exposure through the threat scenarios.				
u	Evaluation criteria (uj)	Weighting of the evaluation criteria	Status quo: S0	Development scenario S1: Lack of Data Libraries and Low Societal Trust	TS1: Geopolitical Turmoil 2033 works with S1	TS2: Data Monopolization and Data Oligarchies 2033 works with S1	TS3: Mass Protests against the use of Big Data 2033 works with S1
u1	Profitability	20.35%	100	82	60	66	67
u2	Product Innovation	19.10%	100	73	59	72.8	64
u3	Social responsibility	15.37%	100	76	68	70	60
u4	Operational Improvement	15.49%	100	79	63	62	76
u5	Expertise	13.70%	100	66.6	53	58	64
u6	System/Industry Environment	15.99%	100	80	70	66	67
Overall rating				**76.10**	**62.17**	**65.80**	**66.33**

f. Evaluation and comparison of the threat scenarios

Again, due to the time constraints of the current stage, the following risks, adaptivity capacity, and vulnerability evaluation of the threat scenarios are based on VS05 team's judgements.



Graph 4. Vulnerability scores, risk, and adaptive capacity for the threat scenarios.

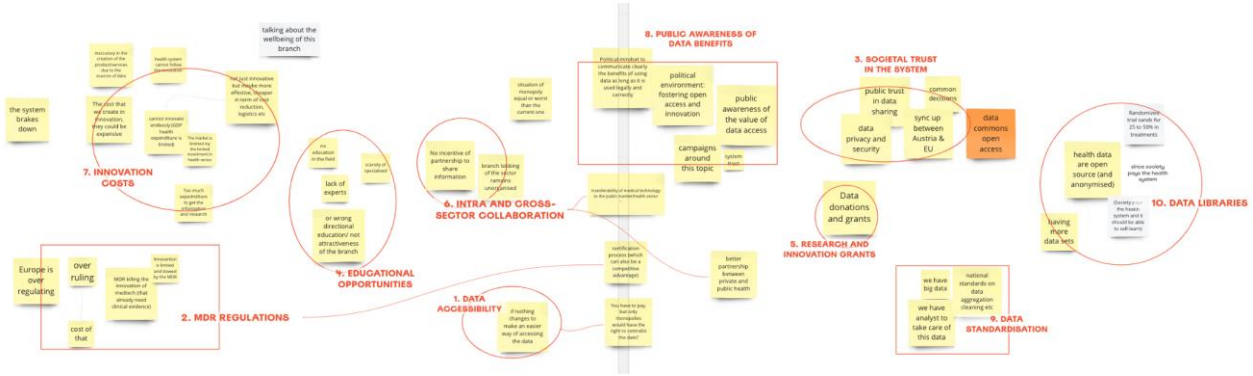
The figure shows us values for the risk, adaptive capacity and vulnerability of the Austrian MedTech system to threat scenarios. The determination of the values are determined using the SVIDT method (Scholz, 2017; Scholz, Czichos, et al., 2020). and build on the DiDaT project (Scholz et al., 2021).

This data table presents an assessment of three different threat scenarios that could impact the Austrian medtech SMEs, under a development scenario labelled "S1: Lack of Data Libraries and Low Societal Trust." Notably, geopolitics turmoil is ranked as the one with highest risk, compared to data monopoly and mass protest. The adaptive capacity column shows the ability of the Austrian medtech SMEs to adapt to each

threat scenario, expressed as a percentage. Most importantly, the vulnerability column shows how susceptible the Austrian medtech SMEs are to each threat scenario. As a whole, the system is considered more resilient to public protest and monopoly threat, but most vulnerable to political turmoils.

5. Discussion

The 2nd Stakeholders Conference allowed the experts contacted to highlight their points of interest on the topic. Moving towards a strong social robust orientation was rather manageable for what was concerning the Status Quo and the immediate future, while the future intervention scenario was harder to draw.



The facilitators have previously clustered 10 impact factors based on the worst and best-case intuitive scenario creation of the previous conference. For each Impact Factor, there are two levels of manifestation (high and low), which determine its positive (high) or negative (low) development within 10 years and are used to construct the potential threat scenarios.

The experts choose 3 of these topics for the following discussion that revolved around their major concerns and the aspect that they consider relevant to create an extensive and coherent picture: Research and Innovation grants, MDR regulations, Data accessibility.

For 2 out of these 3 factors there was a rephrasing:
1. Research, innovation grants and institutions
2. European legislation on licensing and certification processes
3. Data accessibility.

While discussing the first point, the experts pointed out that the level of innovation grants Austria has access to is very low (in some sectors it is comparable to developing countries) because the country is not

pushing towards the obtainment of those to the point where they get access to around the 60% of the funds they could access in theory. At the same time in Austria, there is no counterpart of the German Fraunhofer Gesellschaft to facilitate access to funds, and research grants are more frequently lasting 3-4 years, while the ideal time would be around 7 to reach fruitful results. This point, fundamental for every enterprise, is essential for SMEs since the low cash flow that they have could not allow them to research innovation. An improvement of this point cannot avoid stronger partnerships between SMEs and institutions such as universities.

The second factor was rephrased towards a more inclusive concept of legislation and certification process when the expert mentioned that the European legislation in the field is more demanding than the Austrian one for the regulation, while the Austrian is stronger on the protection. As mentioned in the first conference, the demand for randomised trials to prove the effectiveness (clinical effectiveness) of products can require 15-20 million euros, an unsustainable cost for most SMEs. While for some the regulations, themself and their demanding requirements are the problems, others think that the main issues are the missing professionals in the complementary fields of audit and certification. Most agree on the fact that the legislative framework was not made thinking about the reality of this field and it risks killing the market.

The last factor is particularly concerning for the SMEs in MedTech because, while they acknowledge that regulations are important, access to data and relative freedom in the use of it is essential for innovation. Hospitals are, for instance, very unlikely to share any kind of data with research teams because of the GDPR and usually, there is not even a common database for the public sector itself. In this framework, data collectors have major discretion on how to process data but there is still a lack of standardisation of data between big companies Siemen and Philipps.

With respect to access to data, excludability and rivalry are the major economic dimension, therefore there is very little power in forcing the big providers to share unprocessed data and open access seems to not be a suitable option for many. Moreover, the last point, related to the challenges of the use of data there, is strongly related to the concept of data libraries, that for now are not existing at the Austrian or European level. While the emphasis of the Stakeholders was stronger in the discussion of the problems they find in the field there was an attempt to move on to finding potential intervention paths to better cope with the possible threats.

Data accessibility, according to the stakeholders, requires a discussion on data ownership, to understand if the collectors of the data can be (or not) the only ones to benefit from their collection, or if the customer can decide to whom to give the data collected from them. This will, at the same time, foster competition and innovation. A possible model considered is the one of the German Deutsches Krebsregister (cancer register).

Secondly, policymakers and other stakeholders need to collaborate on shaping the certifications that meet the expectations but are also excludable. This will not translate just into lobbying for the industry interests, but having policymakers work together with industry experts so that there is less gap in the system and fewer bureaucratic processes so that the process becomes more efficient and more relevant parameters when it comes to certification. In parallel, there is a need for more educated experts to audit those rules. At the moment the Chamber of Commerce seems to be the best organ to address this but, when it comes to European legislation, the negotiation requires many compromises. On the innovation side, SMEs should be able to create such innovations that allow them to be interesting and might be bought by big companies.

To increase trust in the system the concept of transparency was introduced as a possible solution. Public campaigns are seen as a possible effective solution, but they should be based on the target audience and the target outcome. Campaigns should also make the public aware of data benefits and the value of sharing anonymised data for the public good.

Contemporary, there should be clear incentives for companies to share the data. And, in this regard, standardisation is necessary, with the IHE consortium being a good example of an approach to standardisation. The top-down approach to standardisation (as to other aspects discussed) fails frequently according to the experts because legislators often don't have the industry knowledge, the reason why they would like it to come from the actors themselves.

In general, the experts acknowledge the need for a white paper on the state-of-the-art and the possible developments of the field. At the same time the discussion, even when heading towards common problems or solutions, has shown how much of the experts' personal and professional perception (eg. centralised or not) was embedded in the concepts reported and the solutions desired.

6. Conclusions

The vulnerability space of Big Data in the context of Austrian MedTech SMEs is an interesting case of the Transdisciplinary real-world problem as it is a highly complex, societally relevant and ill-defined problem that needs intervention from both scientists and industry practitioners. Our team believes that the two Stakeholder Conferences that we co-organised together with facilitators were successful in achieving the objective of the Transdisciplinary Field Research Training program.

These conferences were organised in a manner that facilitated participatory workshops which engaged both science and society, where, as a result of that interaction, both practical and relevant system

challenges and vulnerabilities were identified, systematically analysed, integrated and finally led to comprehensive knowledge integration. The transdisciplinary process also resulted in capacity and consensus building, which was achieved through discussions on system boundaries, the guiding question, and agreeing on common impact factors and evaluation criterias.

If given more time to organise another conference, the team would have focused on facilitating a more in-depth discussion on possible Socially Robust Orientations (SoRo), which could provide a direction on more favourable or obstructive actions for keeping viability of the system.Nonetheless, the proposals generated during the conferences are widely shared by far most of the participating stakeholder groups. The overall aim was to build those orientations based on the vulnerability of the status quo and the threat scenarios with a purpose of contributing to the overall resilience of the system in which Austrian MedTech SMEs operate.

Overall, through the process the team has gained a comprehensive understanding of the coupled human-nature-technology systems (specifically on the example of the real-world ill-defined and locally-contextualised problem) and the effect of transitional processes. We thus believe that the transdisciplinary method proves to be an effective approach in understanding complex societal issues but also a helpful tool in approaching these issues in a way that would be widely shared by many stakeholders, and as a result more socially robust in nature. The team thus aspires to draw the lessons from this experience to later reapply them in their post-graduation practical problem-solving.

7. References

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