



D5.7 Peer- reviewed Paper

On Implementation of RRI in SMEs



RESPONSIBLE INNOVATION
COMPASS



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| Editor | Prof. Doris Schroeder |
| Email | dschroeder@uclan.ac.uk |
| Project Coordinator | Prof Dr. André Martinuzzi Institute for Managing Sustainability Vienna University of Economics and Business (WU Vienna) Welthandelsplatz 1, A-1020 Vienna/Austria http://www.sustainability.eu/ |
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1. Executive Summary

DORIS SCHROEDER

The COMPASS consortium is committed to publishing research results through academic outlets of the highest-quality. In the proposal Springer, Taylor & Francis and Cambridge University Press were mentioned. Editors of all had been approached and interest had been generated. At the same time, the consortium remains open to other opportunities.

One such opportunity arose when a high-profile journal, Sustainability, announced a Special Issue on Responsible Research and Innovation (RRI). Sustainability has an impact factor of 1.789, which is high for a journal that publishes RRI papers. For instance, Taylor & Francis' "Responsible Innovation" has no published impact factor yet.

The decision was taken to submit a paper to the Special Issue from COMPASS. The paper "Implementing Responsible Research and Innovation Practices in SMEs: Insights into Drivers and Barriers from the Austrian Medical Device Sector", written by WU team members Alexander Auer and Katharina Jarmai, was successful. It is added here as Deliverable 5.7.

The paper addresses the question of how RRI can be implemented in Small and Medium-Sized Enterprises (SMEs). It builds on existing knowledge about RRI in business as well as on insights into motivations, drivers and barriers from the related fields of eco-innovation and sustainability innovation. Expert interviews with CEOs of SMEs in the Austrian medical device sector are analyzed to develop insights into the companies' research and innovation activities and potential drivers and barriers for RRI. The findings support the assumption that SMEs are largely unaware of the RRI concept. At the same time, however, it is possible to identify current practices that already operationalize aspects of RRI. It is argued that SMEs could build upon existing practices to further develop ways of being responsible and that implementation of RRI should be in line with specific organizational and contextual factors.

The appendix lists the call for papers of the Sustainability Special Issue.

2. Paper in *Sustainability*

Auer A and Jarmai K (2018) Implementing Responsible Research and Innovation practices in SMEs: Insights into drivers and barriers from the Austrian medical device sector. *Sustainability* 10(1), doi:10.3390/su10010017; available online at <http://www.mdpi.com/2071-1050/10/1/17>

Article

Implementing Responsible Research and Innovation practices in SMEs: Insights into drivers and barriers from the Austrian medical device sector

Alexander Auer^{1*} and Katharina Jarmai²

¹ Wirtschaftsuniversität Wien, Institute for Managing Sustainability; alexander.auer1@wu.ac.at

² Wirtschaftsuniversität Wien, Institute for Managing Sustainability; katharina.jarmai@wu.ac.at

* Correspondence: alexander.auer1@wu.ac.at; Tel.: +43-1-31336-4776

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Abstract: This paper addresses the question of how Responsible Research and Innovation (RRI) can be implemented in Small and Medium-Sized Enterprises (SMEs). It builds on existing knowledge about RRI in business as well as on insights into motivations, drivers and barriers from the related fields of eco-innovation and sustainability innovation. Expert interviews with CEOs of SMEs in the Austrian medical device sector are analyzed to develop insights into the companies' research and innovation activities and potential drivers and barriers for RRI. The findings support the assumption that SMEs are largely unaware of the RRI concept. At the same time, however, it is possible to identify current practices that already operationalize aspects of RRI. It is argued that SMEs could build upon existing practices to further develop ways of being responsible and that implementation of RRI should be in line with specific organizational and contextual factors.

Keywords: Responsible Research and Innovation; Small and Medium-Sized Enterprises; Drivers and barriers; Medical devices; Austria

1. Introduction

The concept of Responsible Research and Innovation (RRI) deals with the conflicting objectives of economic growth, competitive advantage, and the well-being of society [1-4]. Similar to conceptions of eco-innovation and sustainability innovation, RRI is based on the idea that societal well-being and innovative progress can mutually reinforce each other, and that social and environmental considerations can create economic benefits and business opportunities [5,6]. So far, however, evidence on how to implement RRI in businesses is limited [7-9]. Furthermore, insights into business reasons for implementation (such as expected



value-added for business), as well as into drivers to support and barriers that might impede implementation, are scarce [10].

Small and Medium-Sized Enterprises (SMEs) are the focus of this study, as they make up 99% of all companies in Europe and have been under-researched with regard to the practical implementation of RRI (for a notable exception see Pavie and colleagues [11]). The European Commission defines SMEs as companies with less than 250 employees and a turnover of less than EUR 50 Mio [12]. SMEs provide two-thirds of total employment and are responsible for over 50% of value generation in the European Union [13]. Due to their ability to quickly adapt to changing contexts and high levels of internal flexibility, SMEs are considered a driving force of innovation. At the same, SMEs also face considerable constraints with regard to their access to financial resources and their ability to build up organizational structures [14]. It is understandable, therefore, that responsibility issues are not at the core of SMEs' agendas and that they are more concerned about keeping their business running or succeeding on the market [11]. From this, two questions arise: 1) Why do SMEs engage in research and innovation activities and what are the critical factors?; and 2) How do these factors influence responsible business practices in those SMEs and what are potential drivers and barriers for implementing the concept of RRI? The study aims to provide answers to the two research questions formulated above by building on existing knowledge about RRI and findings from related literature on eco-innovation and sustainability innovation. It gathers first-hand insights into research and innovation activities in SMEs and potential drivers for and barriers to RRI from eight expert interviews with CEOs of Austrian medical device SMEs. Interviews are analyzed by means of qualitative content analysis. The findings suggest that the RRI concept can be compatible with practices that are already being implemented in the investigated companies, that moral motivations could open a door to the implementation of RRI, and that policy to facilitate the implementation of RRI practices could benefit from connecting to existing company practices that are already in line with RRI.

Following this introduction, we provide an overview of the current state of knowledge about RRI and draw lessons from pertinent eco-innovation and sustainability innovation approaches. We introduce the context of the Austrian medical device sector and present findings from the interview analysis. Finally, we discuss the most important findings in the context of the existing literature, demonstrate the limitations of the research, and suggest practical implications and further research.

2. Background

2.1 Responsible Research and Innovation (RRI)

While the roots of RRI can be traced back to the early 1990s [15], the concept has gained particular visibility in European policy-making and research communities since 2011. The RRI concept originates in discourses on emerging technologies and research ethics in contested innovative fields, such as nanotechnologies or geo-engineering [15], and has been predominantly driven by European research and innovation policy over the past several years. A first working definition of RRI was proposed by von Schomberg [16] as a: “*transparent, interactive process by which societal actors and innovators become mutually responsive to*

each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)” [16]. In spite of ongoing debates about the definition of RRI [17] and the concept’s continuous development [18], a common, general agreement about the meaning and key aspects of RRI has developed [9] in the form of four dimensions that would lead towards more responsible innovation processes [15,17,19], entailing a collective and continuous commitment to conduct research and innovation processes in an anticipatory, reflective, inclusive (deliberative), and responsive way [19]. At the same time, the European Commission has been promoting responsible research and innovation by funding projects on the thematic elements of ethics, gender and diversity, public engagement, open access, and science education through the previous and current European Framework Programmes “FP7” and “Horizon 2020”.

2.2 Responsible Research and Innovation in business

At this point in time, evidence of how RRI should be put into practice is still limited [18,20,21]. So far, RRI has been “*developed and introduced in a top-down manner by policy makers and scientists*” [8] (p.3) and not yet been translated into practices that are compatible with corporate research and innovation objectives, processes and underlying rationales. A growing number of publicly funded projects and private initiatives have been researching or applying RRI over the past decade [22]; however, only a few of these address businesses specifically [18,22]. More recent studies have aimed to shed light on the implementation of responsible innovation practices in businesses. These studies indicate that businesses in Europe still seem to be operating without an awareness of the RRI concept [18,20,21], but that extant practices, processes and purposes exhibit indications of responsible innovation [23]. Moreover, a growing body of literature has been dealing with questions of how to incentivize or drive companies to adopt the concept [7,10,24] or particular RRI principles [25,26]. First good practice examples of implementation of RRI in business provide a diverse set of company practices; ranging from inclusive governance and a general orientation of company research and innovation towards tackling societal challenges to institutionalized opportunities for anticipation and reflection, as well as to targeted activities aimed at increasing gender balance or fostering science education [27,28].

2.3 Insights from sustainability innovation and eco-innovation

The aim of this paper is to add to this growing body of empirical evidence on drivers of, and barriers to, incorporating RRI in business. It builds on insights from the related fields of eco-innovation and sustainability innovation [29-32]. Similar to the concept of RRI, definitions of sustainability innovation reflect the general difficulty of defining a concept that stretches across social and environmental issues [33]. In contrast, the field of eco-innovation has been clearly defined as being concerned with processes that significantly decrease environmental impacts [34]. Both strands of literature provide valuable insights into the practical implementation of innovative products, processes, services or business models with positive

impact on the environment (and society) by distinguishing between motivations, drivers and barriers.

Businesses' motivations for conducting sustainability innovation are manifold. On the one hand, they imply moral and ethical obligations [35], which center around the morality of products and services, their effects on human beings, and social issues within global value chains [33]. Environmental concerns play an important role when making innovation related decisions [36,37], reflecting society's desire to protect the environment. Economic motivations, on the other hand, cannot be ignored when businesses adopt sustainability innovation. According to Alvarez et al. [38], competitive motivations positively relate to the implementation of environmental practices in a company. Opportunities to improve the productivity or to reduce costs are expected from changes of business processes and products [39]. A more comprehensive approach is offered by Bansal and Roth [40] who suggest ecological responsibility, competitive advantage and the desire to achieve legitimization are the main motivations for conducting eco-innovation. Moreover, the implementation of sustainability is said to strongly depend on the intrinsic motivations of key individuals in companies [41,42].

The sustainability innovation and eco-innovation literature also displays several drivers that are important for their implementation in businesses. Based on technology push and market pull factors from traditional innovation theory, and considerations of environmental policies, determinants can be classified into supply-side factors, demand-side factors and policy framework [29,30]. Supply-side factors include technological and managerial capabilities, tangible and intangible assets as well as knowledge and skills that enable companies to develop eco-innovations. Collaborations with research institutes, private or public agencies, and universities are also acknowledged as important sources of external knowledge. Demand-side factors include market demand [43] and the way the company is perceived by its target group of customers [44]. The regulatory framework includes laws, regulations and standards, such as EMAS or ISO, and is considered an important driver for the implementation of eco-innovations in businesses [39]. In a similar manner, Kesidou and Demirel [45] differentiate between demand-side factors, organizational capabilities and the regulatory framework. The multi-impulse model [31,32] is another explanatory approach of factors "pushing" or "pulling" innovation towards sustainability. This is based on Schumpeter's model of creative response [21] and understands innovation to be the result of the creative performance of actors under specific framework conditions, in which a combination of factors exert influence on the innovation process. It illustrates company-internal (company vision, key individuals) and company-external influences (technological developments, market demand, regulation, civil society) on an innovation process.

Eco-innovation and sustainability innovation literature has further identified a number of barriers that might be useful in investigating factors that hamper the implementation of RRI in business. These include organizational shortcomings, such as a weak technological infrastructure, a lack of commitment from company executives or an oppositional corporate culture [33]. Financial issues, such as budget constraints or unpredictable costs, might also impede the implementation of eco-innovation [46]. Some scholars mention the lack of finance

and seed capital in the market as one of the main barriers to eco-innovation, while others identify the inability of companies to convince investors of their business plans [33]. In the absence of financial resources, the regulatory framework is important for stimulating sustainability innovation. However, respective policies and standards vary considerably across nations and sectors and frequently change over time, making it difficult for companies to plan for the long-term [33].

3. Medical device innovation and the empirical setting

The investigation of potential drivers and barriers for the implementation of RRI in SMEs in one specific context calls for the analysis of a sector that is defined by high innovation rates, a large percentage of SMEs, and a strong level of societal interest in the “responsible” production of products and services. The medical device industry is generally known for being research and development sensitive, being characterized by relatively few leading multinational companies and a great number of SMEs that produce a wide variety of products [47]. While the large firms (such as Siemens, Toshiba and GE) tend to focus on incrementally improving their existing products, SMEs invest in developing radically different products, which are then either patented and licensed to other firms or healthcare providers or bought up by the larger firms [48]. Products associated with medical devices are highly diverse, ranging from high-technology devices, such as surgical and medical instruments or X-rays, to low-technology devices, such as hospital beds, wheelchairs, bandages or syringes [49]. Recently, information and communication technologies (ICT), data processing and digital solutions have transformed the industry, resulting in medical devices that require new ways of interaction and ethical considerations between customers and suppliers.

Innovation processes in the medical device sector have been the subject of much scholarly attention [50-52]. These rely on scientific advancements in other technological fields [53,54] and close collaboration with other companies, as well as with physicians, patients, hospitals and medical research universities [55,56]. Identified factors driving or hampering medical device innovation include the science base, the national healthcare system and intellectual property rights as influences on innovative development [55]. National healthcare systems determine the regulatory framework, funding support, procurement and reimbursement efforts, and demand from the home market [55]. Medical device regulations are important to ensure safety and effectiveness for the patient [56]. Ethical issues, such as access to, and pricing of, medical devices are also considered to be important dimensions of policy-making [57]. Entrepreneurial performance is often driven by the prior experiences of entrepreneurs at incumbent companies [50] and benefits from user involvement in the development of medical devices [58,59].

In Austria, medical devices are a cornerstone of the health industry. In 2014, a total of 487 medical device companies were located in Austria, of which 124 actively performed research, development and manufacturing activities [47]. More than 90% of them are SMEs and work in different technological fields. Innovation activities in the Austrian medical device sector mostly center on digital solutions, such as software for medicine, telemedicine, e-health and electromechanical medical devices, followed by more traditional technological activities, such

as hospital hardware, diagnostic instruments, or therapeutic radiation devices. Funding required for developing these innovations is mostly sourced internally, while external financing has dropped considerably over the last years, mirroring the fact that medical device companies have less access to private and public funding, or are increasingly able to raise capital internally [47]. Public support initiatives promote innovative activities and remedy financial shortcomings to some extent by means of cluster organizations, business incubators or technology transfer organizations. They also provide incentives for starting new businesses, entering collaboration networks or attracting well-known multinational companies to the country. The high density of medical and technical universities and research organizations in Austria enables the production of large quantities of innovation-relevant research output for those companies that are not able to perform research internally. It also ensures the availability of a highly qualified workforce capable of further developing such research and putting it into practice. Several other companies that do not focus exclusively on devices, but supply important components from other technological fields, or provide related services, support the innovative activities of medical device companies in Austria [47]. Their knowledge and technological expertise is at the basis of collaborative endeavors and networking initiatives in this sector.

4. Methods

We apply a qualitative case study approach [60,61] to explore influential factors on research and innovation activities and their role in implementing RRI in a specific contextual setting. Regulations and standards in the Austrian medical devices industry are analyzed as contextual factors. Primary information was gathered in semi-structured, expert interviews with CEOs/founders representing eight highly innovative SMEs. The focus on one specific sector, namely the medical devices industry, allows us to take industry-specific, external factors into account (e.g. regulations and funding schemes). The medical devices sector has been selected for this study because of its immediate societal impact and its particular relevance for the RRI discourse [10,62]. The sector is defined by high innovation rates, a large percentage of SMEs, and a high level of societal interest in the “responsible” production of products and services [47]. Austria is chosen as the geographical area of investigation because the authors’ prior knowledge about the national context facilitates understanding of contextual factors, on the one hand, and access to interview partners, on the other. The focus on Austrian SMEs (i.e. SMEs based in Austria) increases the comparability of the contextual setting.

4.1 Selection of interview partners

A combination of strategies was applied in the search for potential interview partners in order to develop a mostly complete sample. The Austrian Life Science Directory 2015 [47] was scanned for businesses that meet the following criteria:

- Small or medium sized enterprise (i.e. less than 250 employees);
- Flagged as research, development and manufacturing companies for medical devices;

- In-house research, development or innovation activities (i.e. these activities are not being outsourced to labs, universities or other facilities);
- Research, development or innovation activities take place in Austrian locations (and not, for example, in subsidiaries outside of Austria);
- Currently pursuing research, development or innovation activities.

In addition, the selection of companies was confined to directory entries for which a direct contact person could be identified through online searches. This search in the Austrian Life Science Directory was complemented through directed online searches among incubators and accelerators, conference speakers and participants, innovation award winners and undirected keyword searches using different free online search engines. Interview partners were purposely selected to create a diverse set of companies from different Austrian regions, of different sizes (measured by the number of employees) and different levels of maturity (i.e. including start-ups as well as established companies).

4.2 Collection and analysis of information

Eight interviews with CEOs were conducted in February and March 2017 in face-to-face settings (two interviews) or via the telephone (six interviews). In seven of these eight cases, the CEO was also (one of) the founder(s) of the company, which means that all interview partners were well-informed about company context, the business model, and ongoing research, development and innovation activities. All interview partners were willing and able to share information about ongoing research, development and innovation in their companies, and their perceptions about the meaning of “responsibility” within their company context, as well as their assessments of potential drivers for and barriers to different RRI aspects on their companies, or companies working under similar conditions.

The semi-structured interview guidelines were developed in order to guide the interview from a general description of company characteristics (including history, structure and goals) towards company-specific research and innovation processes and practices (including models, regulations, drivers and external cooperation), the interviewees’ partners’ understanding of responsible research and innovation, and, following an introduction of RRI by the interviewer, a discussion of the different RRI elements and potential drivers for and barriers to their implementation. All questions were open-ended.

With the explicit written permission of each interview partner, interviews were recorded and later transcribed. Information was analyzed using qualitative content analysis [63]. This particular analytical technique was chosen because it enables the focus to be placed on specific text passages and extract and combine information relevant to the two research questions specified beforehand. First, interview sections relevant to the three overarching content areas were identified in the transcribed raw material – a) background information on the company, b) motivation for conducting research and innovation and factors influencing research and innovation processes, and c) understanding of RRI/responsibility and assessment of drivers and barriers–. Second, information was extracted and coded by applying deductive category application in four consecutive steps: Definition of units of analysis, definition of categories and characteristics, design of coding guidelines, and display in the form of tables. An excel file

was used to display coded information for each of the 17 categories, which allowed for separate analysis of information in each of the categories and made it possible to compare responses from the different interview partners and identify common and complementary themes and arguments, as well as differences between responses. The presentation of findings in section 5 is structured along the lines of the interview guidelines, arranged into four subsections: Findings from content area a) background information on the company is presented in the introduction to the section; findings from content area b) motivation for conducting research and innovation and factors influencing research and innovation processes are presented in section 5.1 and 5.3; and findings from content area c) understanding of RRI/responsibility and assessment of drivers and barriers are included in sections 5.2 and 5.4.

5. Findings

This section presents findings from the eight expert interviews. After a brief description of the SMEs represented by our interview partners, we describe the identified contextual, organizational and personal factors that influence their research and innovation activities and potentially support or impede the implementation of RRI.

The companies represented by our interview partners have between three and 70 employees and were founded between 1998 and 2016. Five of the companies are located in Vienna while two are based in the western and one in the southern part of Austria. Four companies were founded to exploit existing innovations; two as university spin-offs and two through management buy-ins. The other four companies were founded with the objective to start developing novel technological solutions. All companies are currently developing or selling innovative medical devices in the areas of electro mechanics, in-vitro diagnostics and software for medicine.

It was possible to identify common personal, organizational and contextual factors that influence research and innovation activities in the companies represented by our interview partners; and distinguish them into six categories. These factors are described in the following sections. Personal factors are differentiated into motivations for conducting research and innovation activities (section 5.1) and perceptions of responsibility (section 5.2). Organizational and contextual factors are described according to their actual influences on research and innovation activities in the SMEs represented by our interview partners (section 5.3) and in terms of the role they could play for driving or impeding implementation of RRI (section 5.4).

5.1 Motivations for research and innovation activities

Overall, research and innovation was generally understood to be a means towards increasing the company's success in economic terms. Interview partners reported their company's aim of meeting current or expected future market demand through the creation of new technologies or an increase in market share through improved products. Meeting the needs and expectations of customers was another prominent response. Needs such as the "*wellbeing and safety of the patients*" (interview 13, paragraph 10) or the "*technological improvement of our clients' products and processes*" (interview 11, paragraph 5) were mentioned. In some

cases, in which the companies directly engaged with individual end users, customer needs corresponded to the needs of society. Motivations such as “*improving the quality of life for people*” (interview 4, paragraph 18) or “*responding to societal challenges*” (interview 5, paragraph 8) reflect personal motivations to increase societal benefits through the company’s innovative output. Personal influences include our respondents’ curiosity about their innovation’s potential success in the market as well as its scientific impact, on the one hand, and increasing the individual scientist’s scientific reputation, on the other. This rationale was voiced in particular by respondents who had previously conducted academic research and were curious to find out if their research outputs would succeed in the market. While, as described above, economic reasoning usually triggered research and innovation activities in the company, some of the motivations put forward by our respondents imply both responsibility and economic reasoning. The intention of one interviewee, for example, “*to meet the needs of all our stakeholders*” (interview 9, paragraph 4) not only indicates a motivation to fulfill the financial interests of investors, but also implies the maintenance of the jobs of their employees.

5.2 Perceptions of responsibility

In another open-ended question respondents were asked about their understanding of the concept of RRI and “responsibility” in general; with respect to their company. The aim of this question was to give our interview partners the opportunity to express their understanding of their company’s responsibility before providing them with our definition (as laid out in section 2.) and whether they had already come across the RRI concept. We were curious to see what RRI aspects could be identified in our respondents’ different responsibility perceptions, what they consider as responsible innovation and the extent to which such responsibility aspects are taken up in their research and innovation processes. Overall, responses suggest that our interview partners were not aware of the RRI concept but that they have been implementing particular aspects of RRI without being aware of the fact that these were part of a particular research and innovation policy. Companies, for example, demonstrate their *anticipative and reflective* capabilities by considering potential negative consequences of their research and innovation, by anticipating future challenges and opportunities resulting from new regulations or directives, or by reflecting upon their target groups’ needs and values. Or as one interviewee put it: “*As an entrepreneur I’m always trying to anticipate what comes next, what difficulties, what obstacles or what challenges same as opportunities. So this is a permanently ongoing process [...].*” (interview 6, paragraph 17). The customization of innovation processes according to the needs of their different customers and their consideration of different societal challenges, such as migration or a two-tier health service suggest a certain degree of *diversity and inclusion* among the firms interviewed. The *responsive and adaptive* character of the SMEs’ innovation processes becomes evident in their ability to quickly adapt to changing market conditions. The high degree of flexibility was indeed considered essential for succeeding in the market and meeting their customers’ interests; an ability that often distinguishes them from their larger competitors. *Openness and transparency* of research and innovation processes become evident in the respondents’ desire to avoid the reproduction of already existing technologies. Openness in the sense of open access to their research results,

however, is also considered to restrict innovation activities as it is impractical for gaining a competitive advantage, and eventually achieving sufficient returns on investment. Overall, we find that our respondents not only consider profit related and economic reasons when making research and innovation decisions, but also the possibility to “do something good” (interview 6, paragraph 10).

5.3 Factors driving or impeding research and innovation

Overall, it was possible to identify organizational and contextual factors of high importance for research and innovation activities in the SMEs represented by our interview partners. These factors are largely in line with findings from the literature introduced in section 2 but are specific with regard to their empirical setting as outlined in section 3. The factors that drive or impede research and innovation in the SMEs are distinguished into six categories (see Table 1) and described in the following subsections.

Table 1. Drivers for and barriers to innovation

| Factor categories | Drivers supporting innovation | Barriers obstructing innovation |
|---|--|--|
| Regulatory framework | <ul style="list-style-type: none"> - Regulations drive demand for technologies - ISO certification and laws require implementation of quality management systems - ISO certification process leads to market focus | <ul style="list-style-type: none"> - Regulatory and certification processes require financial and personnel resources - Insufficient information about regulations and processes |
| Funding and finance | <ul style="list-style-type: none"> - Personal and public funding offset lack of financial resources | <ul style="list-style-type: none"> - Limited access to financial resources due to risk aversion of investors - Cash flow problems due to lack of marketable products |
| Market orientation | <ul style="list-style-type: none"> - Knowledge about technological trends inspires new innovation - Learning from competitors, partners and other stakeholders - Understanding market trends for developing innovation for the market | |
| Customer knowledge | <ul style="list-style-type: none"> - Knowledge about the needs and requirements of customers - Inspiration for innovative ideas and technological improvement | <ul style="list-style-type: none"> - Customer engagement required during certification procedures and clinical tests |
| Management and organizational structures | <ul style="list-style-type: none"> - Structures facilitate distribution of tasks and | <ul style="list-style-type: none"> - Lack of management and organizational structures due |

| | | |
|--|--|--|
| | internal procedures (e.g. certification) | to lack of entrepreneurial experience |
| | | - Lack of planning of innovation processes |
| | | - Unable to produce marketable results |
| External knowledge from collaborations and networks | - Offset limited internal structures and knowledge | - Limited access to highly skilled employees |
| | - Access to management and technical know-how | - Dependency interests of different stakeholders |

5.3.1 Regulatory framework

The regulatory framework generally plays a crucial role in the different companies' ambitions to generate innovation. It not only governs the direction of their technological development but also influences how research and innovation is managed. One interviewee argued that: “[...] *the wrong therapy or [if we] make the wrong treatment with this patient and eventually the patient might be harmed or even die. And then we cannot say, sorry there was a little mistake, I copied the wrong algorithm or I had a headache. This is not possible. This is why we are in a regulated business.*” (interview 11, paragraph 13). Specific ISO certifications, such as ISO 13485 and medical device laws and their direct impact on research and innovation processes were pointed out by our respondents. The ISO 13485 certification requires them to have a quality management system and quality control procedures in place to help document and reduce potential risks of innovation processes. The interviews also revealed that the ISO certification process can stimulate innovative activities, eventually guiding innovative outcomes more towards market release. Such certification procedures are usually dealt with at early stages of the innovation process in order to avoid delays and an overload of demand on personnel resources when entering the market. They also involve clinical testing and ethical compliance checks to ensure the effectiveness of medical devices and the physical integrity of the patient. However, the regulatory framework is considered not only to drive innovation, but also to cause delays in the companies' research and innovation processes due to insufficient information about regulations and a lack of financial and personnel resources to cope with them.

5.3.2 Funding

Funding turned out to be one of the crucial factors influencing research and innovation. Interview partners report considerable problems in accessing internal and external funding sources. During the early stages of their respective company's lifetime, they reported considerable cash-flow problems, which was primarily attributed to the fact that large finance providers are likely to refrain from investing in medical device SMEs until they have developed a marketable innovative product and the risks and benefits are more predictable. Or as one interviewee stated: “[...] *in-vitro diagnostics is a slow moving, many regulatory hurdles, type of business and is not very easy and attractive for venture capitalists to go into that, at an early stage. It gets more interesting when you are on the market.*” (interview 8, paragraph 3).

Personal funds and public funding sources are a popular alternative. In addition, pre-seed and seed-funding from local or national funding agencies has proven attainable and useful to our respondents. External funding from private investors and business angels was named as another opportunity once a company matures, the first research results become visible and the company's market viability can be assessed. Private investors and business angels are reported to have two important functions: First, they provide larger amounts of funding that allows SMEs to focus on their research and innovation activities, and second, they often contribute expertise and advice on how to turn academic research and innovation into marketable products and services.

5.3.3 Market orientation

Knowledge about the market was identified as another crucial factor influencing innovation processes. This includes understanding of technological trends, market dynamics and the needs of different stakeholders in the market. Knowledge about these issues is considered indispensable for developing marketable innovative products and services. According to our interview partners such knowledge usually results from previous working experiences as academics or professionals in the medical devices field. As one interviewee puts it: *“So the innovation was driven by looking at available technology, which we have a deep understanding because we have been working for the market leader. They have about 85% global market share. And we know all the technologies out there and we did our own analysis of what type of technology we would like to have to overcome all the problems with existing concept and technology.”* (interview 8, paragraph 5). Interestingly, knowledge about the market is not only considered to be essential for directing research and innovation activities but also as an important source for innovative inspiration.

5.3.4 Customer knowledge

The importance of customer knowledge for innovation activities was emphasized by different respondents. Many of them put forward the idea that the implementation of a medical technology requires a deep understanding of their customers' needs. Products or technological improvements of already existing products that would not fit their customers' requirements would simply have no impact on the market. For that reason, the companies cooperate closely with their customers during the whole research and innovation process. As described in the words of one interviewee: *“[...] we see how the needs emerge, how they change, we get feedback from customers, this drives also our product development and we have ideas.”* (interview 11, paragraph 5). The ISO certification and respective quality standards further require the companies to continuously gather feedback from their customers and conduct clinical tests with hospitals and doctors.

5.3.5 Management and organizational structures

Management and organizational structures facilitate the distribution of tasks and internal procedures. Our respondents describe regulated internal procedures and distribution of tasks to have a positive influence on their innovation activities. They facilitate the implementation of

quality management systems and other technological standards necessary to fulfill medical device-related regulations. However, a lack of time and personnel resources prevents them from developing such structures within the companies. Without these structures: “*Contracts, ethic commission, etc., hard to do with a small company in a small environment where you do not have a legal department but you do need to handle all this.*” (interview 6, paragraph 6). However, as a positive outcome of this lack of structure, companies name high levels of flexibility in adapting to the needs and expectations of different customers and stakeholders.

5.3.6 External knowledge from collaborations and networks

External knowledge from collaborations and networks plays an important role in our respondents’ innovation processes. Highly skilled employees are considered important for turning innovative ideas into concrete research and innovation results. Technical know-how, knowledge about Intellectual Property Rights (IPRs) and the ability to absorb and implement external knowledge such as customer feedback in innovation processes are of particularly high value in these companies. Interview partners report a lack of internal technological capabilities and management expertise and, consequently, a dependency on external knowledge about markets, customers, IPRs and technological expertise provided by universities, other businesses or funding agencies. External knowledge providers often come from the CEOs’ personal networks. This means that the CEOs’ previous working experiences strongly influence the selection of collaboration partners and the ways research and innovation processes are managed. One interviewee stated: “[...] *from my former company, I still have a strong network and I can use this network and there is long term relationships and trust on both sides.*” (interview 6, paragraph 6). Collaboration with universities allows further development of the technological aspects of innovative products, and collaborations with large companies are used to open up markets, and access international distribution networks and managerial advice or financial resources.

5.4 Potential drivers for and barriers to the implementation of RRI

Potential drivers for and barriers to the implementation of RRI in the companies represented by our interview partners can be distinguished into the same six categories of factors as described in section 5.3. These potential drivers and barriers (see Table 2) are described in the following subsections.

Table 2. Potential drivers for and barriers to RRI

| Factor categories | Drivers supporting implementation of RRI | Barriers obstructing implementation of RRI |
|-----------------------------|--|--|
| Regulatory framework | <ul style="list-style-type: none"> - RRI implementation required by law - Threatened fines for not meeting RRI standards - Governments promote RRI and a comprehensible | <ul style="list-style-type: none"> - Unclear regulatory focus and changing regulatory framework at different geographical scales - Theory-driven regulations divorced from reality |

| | | |
|--|---|--|
| | <ul style="list-style-type: none"> development strategy for SMEs - Information about RRI and ethical support from regulatory bodies | <ul style="list-style-type: none"> - Lack of information and support measures about RRI |
| Funding and finance | <ul style="list-style-type: none"> - European and national funding agencies require attention to societal and gender aspects - Increased access to European and national funding when considering RRI aspects | <ul style="list-style-type: none"> - Higher innovation costs expected from RRI implementation - Additional financial resources required for RRI implementation |
| Market orientation | <ul style="list-style-type: none"> - Future economic value expected from taking up RRI - Growth potential and benefits expected from taking up RRI - Expected cost reductions from implementing RRI | <ul style="list-style-type: none"> - Lack of a qualified female workforce in the labor market - Cost and success pressures paired with uncertain outcomes from RRI - Shareholder value and profit maximization thinking paired with unclear innovative and profit potentials |
| Customer knowledge | <ul style="list-style-type: none"> - Increased company reputation and visibility among (potential) customers expected from complying with RRI - Compliance with their customers' internal rules (certain RRI aspects) | <ul style="list-style-type: none"> - Increased customer engagement can hamper finding consensus among stakeholders |
| Management and organizational structures | <ul style="list-style-type: none"> - Ethical and responsible thinking and societal considerations of founder, managers or employees to comply with RRI aspects - Employees transfer understanding of responsibility from previous companies - Internal codes of conduct advocated by management require employees to comply with RRI | <ul style="list-style-type: none"> - Lack of knowledge about RRI and how to implement RRI aspects requires strong personnel efforts - Personal attitudes and experiences of founders conflicts with RRI aspects - Lack of governance structures in SMEs affects uptake of RRI - Long-established (sometimes conservative) governance structures prevent the introduction of structural change in companies - Implementation of RRI takes additional efforts and personnel resources |
| External knowledge from collaborations and networks | <ul style="list-style-type: none"> - Compliance with their innovation partners' responsibility rules or codes of conduct (large RRI advocates) | <ul style="list-style-type: none"> - Innovation partners advocate their own interests and affect decision making and the likelihood of resistance to RRI |

-
- Increased company reputation and visibility among potential collaboration partners expected from complying with RRI
-

5.4.1 Regulatory framework

In the specific context of our interview partners, regulations can be considered as one of the most effective factors driving the implementation of RRI. Such regulations could be enforced in the form of RRI standards that companies have to conform to; such as in the case of gender quotas in public sector-related companies, or in the case of ethics clearance for clinical studies. The promotion of RRI aspects and its benefits are considered necessary for a broader uptake but should be aligned with the needs of SMEs. Respondents emphasize the fact that they would require additional information about RRI and its benefits as well as clear guidance on how to implement the concept into their research and innovation processes. This lack of information and support is highlighted as a main barrier to implementing RRI. Respondents further criticize a generally fast-changing regulatory framework and the complexity of policy processes at different geographical levels. According to one interviewee who stressed the fact that: “[...] *the people who make these rules and regulations they act from a too much further position which is too much into theory. And not into living practice.*” (interview 11, paragraph 17) companies also question the theoretical conception of RRI, and its insufficient translation into practicable measures for SMEs.

5.4.2 Funding and financing

Financial resources are not only considered essential for successfully doing research and innovation, but also for introducing the concept of RRI to SMEs. A lack of financial resources, particularly in the early stages of company development, increases our respondents’ willingness to implement RRI aspects in return for easier access to financial support; or as one interviewee stated: “[...] *if there are external motivations like access to funding and so on then this is always a driver to make you consider these things and put some more policies or whatever on paper for your employees to follow.*” (interview 8, paragraph 25). They also refer to European and national funding agencies that already promote the consideration of societal impacts or gender quotas. According to one respondent: “*a further uptake of RRI aspects within public funding requirements would further push its implementation.*” (interview 12, paragraph 25, translated from German to English). At the same time, however, stricter requirements for RRI in research and innovation processes are expected to put pressure on the companies’ financial resources; it might cause an increase in their cost structure and a need to hire more qualified staff able to translate responsibility aspects into beneficial innovation and organizational structures.

5.4.3 Market orientation

Respondents share the view that the implementation of RRI in practice will be strongly dependent on market dynamics. As described above, research and innovation activities are generally pursued to gain positive future economic value and long-term profits (see section 5.3.1). A clear incentive for the respondents to implement RRI in their companies would be the prospect of growth or reduction of costs. Gender aspects are mentioned as a potential barrier by one interviewee who refers to the relatively small pool of qualified female workers with a technical background in the medical device market, which would make it difficult to fulfill a gender quota. In this context, one respondent also mentions that: *“the “cost for developing medical products will rise incredibly and small companies will not be able to afford it. So I’d say, a discrimination against small companies.”* (interview 11, paragraph 16); large competitors tend to have easier access to sparse financial and personnel resources, thus aggravating the disparities in the situation even further. In addition, a potential increase of costs and the continuous pressure to succeed on the market impede these companies in implementing RRI in their research and innovation processes.

5.4.4 Customer knowledge

Respondents claim that better access to customers would increase the likelihood of RRI implementation among SMEs. The important role assigned to customers throughout the research and innovation process makes these companies open to approaches that help them improve and intensify collaboration. A potential increase of company reputation and visibility among (potential) customers would increase our respondents’ willingness to implement RRI. One interviewee stated: *“[...] if it is necessary to portray yourself responsibly and we would expect a benefit from that we would agree to that.”* (interview 5, paragraph 26, translated from German to English). Internal codes of conduct imposed by their customers are also considered important drivers for adopting RRI principles in the research and innovation process. When customers are large companies they could drive the implementation of RRI by requiring them to adhere to ethical codes of conducts, training or other quality procedures. In contrast, the increased involvement of customers in the research and innovation process is also expected to hamper consensus finding among the companies’ different stakeholders. This would not only drastically slow down their research and innovation process but also use up a large proportion of their financial and personnel resources.

5.4.5 Management and organizational structures

Management and organizational structures are considered important to facilitate the uptake of RRI aspects. These structures could drive RRI by specifying responsibilities for taking ethical, social or other actions into account and support the commitment of employees to implementing RRI. A lack of such structures makes it difficult to assess risks and benefits and would impede the implementation of RRI. The personal attitudes and prior experiences of founders, managers or employees can heavily influence the way RRI aspects are considered, and whether they are expected to yield positive effects on innovation processes or outcomes. One interviewee also emphasized the important role of company executives for introducing the

RRI concept to a company's employees: “[...] *this is also what our employees are aware of and what I tell them.*” (interview 11, paragraph 13).

5.4.6 External knowledge from collaborations and networks

Our respondents expect external collaboration and networks to be potential drivers of RRI. This includes enforced compliance with collaboration partners' responsibility rules or codes of conduct. Some of the respondents have already been confronted with RRI aspects through collaboration with universities and large business partners. One interviewee reported: “*I know from the companies we worked in the past with, they always had these annual or half yearly integrity training which was basically a computer questionnaire that you had to fill out [...].*” (interview 8, paragraph 12). Codes of conduct and ethics trainings were most prominently mentioned by our respondents. According to some of our respondents, RRI would also attract attention among SMEs if the integration of RRI principles would yield higher visibility and a better reputation among potential and existing partners and customers. At the same time, however, they point out that external knowledge providers might be opposed to the concept of RRI.

6. Discussion of findings

This study investigates research and innovation activities in the Austrian medical device sector and links them with RRI practices. In this way, it adds to the growing body of literature on the implementation of RRI in business [7,10,11]. Understanding of the potential drivers and barriers is shaped by extant knowledge about the organizational and contextual factors that drive or impede eco-innovation and sustainability innovation [30-32]. We find that in the case of RRI, traditional theoretical explanations which build on external and internal influences on research and innovation activities are helpful. The main findings are discussed below.

6.1 Practicability of the RRI concept

Overall, our interview partners had no prior knowledge of the RRI concept. This supports previous observations that SMEs are still largely unaware of RRI [7-9,18,20,21]. When the different elements of the concept (see section 2) were explained to them, however, they had no difficulties in relating them to their company activities and in discussing potential enabling and obstructing factors. Thus, while the concept itself was unknown to them, it was easy for them to start thinking about the different elements that constitute it; even if they did not necessarily see advantages in implementing all of them. The only RRI element that our interview partners had difficulties relating to was the thematic element of “science education”, as described by the European Commission [64]. Furthermore, interview partners mentioned a range of different practices that are already being performed in their respective companies and can already be considered as practices of the different elements that make up RRI. This includes practices to anticipate the potential consequences of research and innovation activities on customers and end users (i.e. patients, doctors, and hospitals), the inclusion of many different stakeholders to compensate for the lack of internal resources, as well as the timely response to new or changing customer needs. As described in section 3, the development and use of medical devices are

strongly regulated [57] and the companies represented by our interview partners must adhere to a variety of national standards and EU directives. Their accounts of high ethical standards in the medical devices sector reflect previous observations [58]. Engagement of particular stakeholder groups is common practice in the sector, where close contact with customers and the end user (i.e. the patient) is necessary to learn about respective needs, expectations and technological trends. Gender aspects become relevant when applying for public funding, which is an essential source of finance for most SMEs. These and other examples suggest that the RRI concept can be compatible with some of these companies' existing practices.

6.2 Profit-oriented versus moral motivations to engage with RRI

Recounted reasons to engage in research and innovation activities generally include profit-oriented elements, but also refer to the generation of positive impact on customers, society, or the environment. In relation to previous assumptions that corporate innovation needs to be developed through collective efforts beyond mere corporate self-interest [17], we find that the representatives of our group of Austrian medical device SMEs are aware of responsibility issues and are, in general, interested in increasing their company's positive impact on them. Recurring aims are the improvement of patient treatments or a quality improvement in medical devices used by doctors and in hospitals. Similar findings are shown in studies of other sectors, such as in the case of ICT for aging people, or the food industry [10,65]. Similar reasons have been documented for companies that develop eco-innovations or sustainability innovations and are often referred to as moral or intrinsic motivations [33,35-38,41,42]. This finding suggests that while an expected increase in profits would likely be a good reason for companies to start looking into ways to implement RRI, it does not have to be the only starting point. Moral motivations could open a second door to the implementation of RRI in companies.

6.3 Potential driving and impeding factors for the implementation of RRI

When the different process and thematic elements that make up the RRI concept were explained to them, our interview partners had no difficulties in discussing these elements, and could thus provide an expert, first-hand perspective on the potential driving and impeding factors for the implementation of RRI in SMEs in the Austrian medical device sector (see Table 2 in section 5.4). It does not come as a surprise that the potential drivers and barriers they mentioned relate to the same factors they had already identified as being influential on research and innovation activities in their respective companies (see Table 1 in section 5.3). Overall, the different descriptions and lines of argumentation are complementary and do not contradict one another. Potential drivers and barriers can easily be integrated into categories developed in the literature on eco-innovation and sustainability innovation [29,30,33]. We would like to emphasize that, in the perception of our interview partners, all factors have the potential to act as either drivers or barriers, depending on other situational and contextual factors. While the prominence of the regulatory framework (including laws, regulations and required certification) as a potential driver of RRI relates to its significance in previous studies on eco-innovation and sustainability innovation [29,32], it is, for example, equally emphasized as a potential barrier to the implementation of RRI when the regulatory focus is unclear, when it is

subject to frequent adjustments, or when information about practical implementation measures is lacking. External funding, as a second example, was pointed out as an important potential driver for the implementation of RRI by making adherence to specific practices a requirement for funding. At the same time, however, interview partners were wary of stricter requirements for public funding in putting additional strain on their already limited financial resources. As a final example, the personal attitudes and prior experiences of founders, managers or employees are attributed with the ability to heavily influence the way RRI aspects are considered within the company, and whether they are expected to yield positive effects.

Overall, and in line with other authors' observations [10], an implementation of RRI practices is more likely to be considered a benefit for a company if it is aligned with existing company practices and structures [11]. In the case of the Austrian medical device sector, an implementation of RRI practices could, for example, connect to the extant high level of ethical requirements and standards for products on the market, as well as to existing practices of user, customer or expert engagement in the idea-generation and development of novel products, processes or services.

6.4 Limitations and further research

The research approach allowed us to gather valuable insights into research and innovation processes in one particular sector, while the generalizability of the findings is limited by the qualitative nature and the geographic scope of the study. The influential factors discussed according to the six categories in sections 5.3 and 5.4 should not be taken as an exhaustive list of factors that influence research and innovation processes. Further studies could, for example, explore sectors that are characterized by little immediate interaction between innovation producers and the users of the innovation, and explore the impact of such contextual environments on the perceived drivers for and barriers to RRI. It would also be useful to further investigate the ambiguities arising within different factor categories to better define opportunities for practical implementation of RRI in SMEs. Research and innovation policy-makers could build on these findings, and on previous knowledge from the fields of eco-innovation and sustainability innovation, to boost implementation of RRI in companies, and try to connect it to existing practices within a particular sector that already actively reflects upon elements of RRI.

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Appendix: Special Issue Information

For several years Responsible Research and Innovation (RRI) has been widely discussed, especially in the European context, but also in academic conferences and publications. Numerous EU projects under the FP7 framework, as well as in the Horizon 2020 program, have been conducted, or are currently ongoing.

Despite this significant attention, the focus of RRI was mainly on publicly funded research and the generation of recommendations for policy. There was less attention on practical ways of implementing RRI in companies. Due to the importance of private businesses in undertaking research and in particular innovation, the RRI discourse should cover the role of industry more explicitly. A key question is how RRI relates to other activities that may be of ethical or social relevance, such as corporate social responsibility.

This Special Issue of Sustainability therefore offers a forum for dissemination and discussion of the relationship between RRI and industry. Our definition of industry is broad, including companies of all sizes and industries, including the service sector. We welcome conceptual, empirical or experimental results that are discussed in a national or international context.

Suggested topics for this Special Issue on RRI are (list not exhaustive):

- RRI in Multinational Companies
- RRI in Small and medium sized companies
- RRI in start-ups
- Industry-specific RRI implementation, e.g., healthcare, ICT, etc.
- Linking policy and management levels of RRI
- Engagement of RRI Stakeholders
- RRI in an international context, e.g., Europe vs. US
- RRI and Sustainability
- RRI and Corporate Responsibility
- Methodological aspects of RRI
- Limitations and challenges of RRI