Responsible innovation as a driver of regional policies and innovation and entrepreneurial practices: The context of digitalisation of healthcare and welfare services

by

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Raj Kumar Thapa, Stavanger, 2023

Summary

This thesis explores the concept of responsible innovation (RI) and its implications for regional policies, innovation, and entrepreneurship policies and practices in the context of healthcare and welfare services. RI is a concept that emerged in the wake of widening grand societal challenges and is developing and spreading quickly to govern research and innovation on society's needs, values, and expectations. RI emphasises the reflection of purpose, process, and outcomes of innovation and entrepreneurship policies and practices such that they contribute to addressing grand societal challenges and create a broader societal impact.

There is a growing belief that RI dimensions of inclusion, anticipation, reflexivity, and responsiveness can offer a valuable tool. Thus, RI practices could enable policymakers, firms, and stakeholders within the regional innovation ecosystem to interact to address grand societal challenges. However, RI has stalled at articulating a governance process with a strongly normative loading without clear, practical guidelines for implementation strategies and mainly concentrated on publicly funded research projects. RI scholars argued that RI and its aspiration could only be achieved if integrated into policies and practices. Furthermore, because firms and the private sector are the primary drivers of innovation, they need to acknowledge the significance of RI practices in innovation and business practices. However, most firms and policymakers are either unaware of RI or find implementing RI in

research, innovation, and entrepreneurship policies and practices challenging.

Furthermore, RI emphasises the inclusion of micro, meso, and macro levels of stakeholders in the innovation ecosystem for desirable, sustainable, and responsible innovative outcomes and broader impact. However, existing theoretical frameworks do not fully account for whether, how, and why firms adapt and practice RI in innovation and entrepreneurship. Thus, given that firms are embedded in the regional context, there is a need to understand RI and its role in shaping the purpose, process, and outcomes of innovation and entrepreneurial policies and activities to achieve overall regional goals.

This thesis addresses these problems in the context of healthcare and welfare services, which are under immense pressure to ensure accessible, equitable, and sustainable services, primarily due to demographic and ecological changes. The emerging digitalisation and innovation in digital technology bring several potentials to address societal challenges, including healthcare and welfare service challenges. However, digital innovation might also raise privacy, safety, and security issues. RI can play a vital role in addressing these issues and drive research and innovation to benefit society.

The empirical setting is the context of digital innovation in healthcare and welfare services, particularly in the Western region of Norway. This region established the Norwegian Smart Care Cluster (NSCC) in 2013 to promote digital healthcare and welfare provisions to citizens and

contribute to regional and national economic growth. The cluster comprises approximately 290 organizations, including 194 private firms working on digital innovations in healthcare and welfare services.

This thesis employs a qualitative approach with two different research designs between Paper I and Papers II, III, and IV. It utilizes empirical data collected from the nine firms belonging to the NSCC and the diverse set of stakeholders, including the cluster administration, university researchers, municipality representatives responsible for procurement and implementation of health and welfare services, healthcare professionals, and regional politicians. Paper I is a systematic literature review based on peer-reviewed journals. Papers II, III, and IV are case studies conducted using semi-structured interviews and secondary data gathered from various sources. The case studies and data gathered in this thesis take an exploratory approach. The approach is split between multiple case studies in Papers II and III and a single case study in Paper IV.

The four research papers together answer the overarching research inquiry, ‘How does the RI approach facilitate regional policies and innovation and entrepreneurship practices in firms toward increased societal impact?’ The individual research papers apply different theoretical perspectives together with RI. In so doing, the thesis contributes to theory, practice, and policy in RI, innovation, and entrepreneurship.

Paper I explores RI and its implications for regional policies in the context of sustainable regional development. It sheds light on the implications of RI for regional policies and vice versa for sustainable regional development. The paper also indicates that reflection on the purpose, process, and outcomes of innovation and entrepreneurship policies and practices is crucial to achieving sustainable regional development.

Papers II and III outline the RI integration mechanisms in innovation and entrepreneurial processes. Paper II explicitly explores the inclusion dimension at different stages of the innovation process and contributes by elaborating on the role of RI practices in the innovation process in achieving optimal desirable solutions for societal challenges. Paper III explores RI in venture creation and how it facilitates firms' building opportunity confidence for socially responsible venture creation and firm development.

Paper IV reflects on the outcomes of responsible innovation and entrepreneurial processes and on the mechanism for creating organizational sustainability and expanding positive social impact.

The findings of the thesis suggest that RI can facilitate innovation and entrepreneurship policies and practices to achieve regional goals with increased societal impact. However, RI integration in innovation and entrepreneurial practices faces several challenges, especially for start-ups and entrepreneurs with limited resources and external networks. Potential solutions to grand societal challenges might face barriers to

development in such situations. Therefore, supportive mechanisms should be in place to motivate firms and entrepreneurs to integrate and practice RI in their innovation and entrepreneurship activities.

Overall, this thesis contributes to extending knowledge of the applicability of the RI concept in regional policies and firm practices. At a theoretical level, first, it synchronizes RI with regional studies. Second, it provides insights into how reflections on the purpose, process, and outcomes of innovation and entrepreneurial policies and activities can lead to inclusive and responsible outcomes in the digital healthcare and welfare service sectors and address current and future healthcare and welfare service challenges. The practical implication is that firms and entrepreneurs can leverage RI in their innovation and entrepreneurship processes to find solutions through need–solution interaction and build opportunity confidence to enhance the adoption and diffusion of innovative solutions. In so doing, they can reduce the risk and uncertainty of failure.

Similarly, policies should support firms and entrepreneurs, especially young start-ups, with interventions and initiatives that provide training on RI principles. While the thesis focused on regional policies and firm practices, it looked at only one sector and particular region. Therefore, future research could seek insight from other regions, contexts, and industries.

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Paper I: Thapa, R. K., Iakovleva, T., & Foss, L. (2019). Responsible research and innovation: A systematic review of the literature and its applications to regional studies. European Planning Studies, 27(12), 2470-2490

Paper II: Thapa, R. K., & Iakovleva, T. (2023). Governing digital innovations for responsible outcomes – The case of digital healthcare and welfare services (Submitted to the Journal of Innovation and Entrepreneurship).

Paper III: Thapa, R. K., & Iakovleva, T. (2023). Responsible innovation approach in venture creation and firm development: The case of digital innovation in healthcare and welfare services. Journal of Responsible Innovation (Published online, 7 February 2023).

Paper IV: Thapa, R. K., & Iakovleva, T. (2019). Responsible research and innovation: Innovation initiatives for positive social impact. In Responsible Innovation in Digital Health. Edward Elgar Publishing.

1 Introduction

1.1 Background, research question, aim, and contributions

This thesis explores the concept of responsible innovation (RI), its implications for regional policies, its operationalisability, and its implications for innovation and entrepreneurial activities in firms, specifically in the context of digital innovation in the healthcare and welfare service sectors.

Responsible innovation (RI) is an emerging concept in the governance of innovation and entrepreneurship to align them with society's values, needs, and expectations and address societal challenges (von Schomberg, 2011; Owen et al., 2013; Stilgoe et al., 2013). Although it has dominated the policy discourse, including innovation policies (Fitjar et al., 2019; Jakobsen et al., 2019; Owen et al., 2012), it also applies to innovation and entrepreneurial activities. It has particular relevance to grand societal challenges (Lund Declaration, 2009; Kuhlmann & Rip, 2014; Owen et al., 2021b; Owen & Pansera, 2019).

Healthcare and welfare service challenges are among the grand societal challenges exacerbated by changing demographics, such as the ageing population, environmental pollution, and changing lifestyles (WHO, 1996; Saltman et al., 1997). On the one hand, public spending on healthcare and welfare services is increasing (OECD, 2018), exerting an additional economic burden on governments (Wallace, 2013). On the

other hand, the demand for efficient healthcare services and patients' expectations are growing, putting extra pressure on governments to increase healthcare budgets (Iakovleva et al., 2019a). Furthermore, an ageing society will need more skilled workers to meet increasing healthcare and welfare services demands and overcome healthcare disparities in and between regions (Official Norwegian Reports, 2009, 2011; OECD, 2017). This brings into question the inclusivity and sustainability of healthcare and welfare services. Governments and policymakers have turned to innovation and entrepreneurial activities to address societal challenges.

With the emergence of digital technology, there are growing expectations that digital innovation and entrepreneurship will enable innovative, affordable, and cost-effective solutions for public healthcare and welfare services (Bessant et al., 2017; Christensen et al., 2017). However, concerns have been raised about the 'dark side' of digital innovation and entrepreneurship (Jirotka et al., 2017; NorSIS, 2017) and their intended and unintended consequences, such as privacy, safety, security, and the digital divide (Warschauer, 2004; van Dijk, 2006; Hofmann, 2013; Stahl, 2014; Liu et al., 2016; Nilsen et al., 2016).

Furthermore, healthcare involves diverse interest groups and multiple interrelated causes and consequences. Therefore, providing healthcare is a complex challenge, and producing disciplinary knowledge cannot reduce the associated risk (Marschalek et al., 2022; Timmermans et al., 2020). A classical linear techno-scientific approach to innovation and

entrepreneurial activities may not be appropriate in such a context (von Hippel & von Krogh, 2015).

Additionally, regional policies are vital in driving innovation and entrepreneurial activities in regions to boost regional competitiveness and contribute to addressing societal challenges. However, the evidence of increasing disparities between and within regions due to uneven distribution of gains from innovation (Iammarino et al., 2019) often challenges the ability of conventional regional policies to address the growing societal challenges in regions. Accordingly, governments and policymakers are seeking regional innovation and entrepreneurship policies to stimulate innovation and entrepreneurial activities in response to societal challenges in and between regions (Fitjar et al., 2019).

RI has been proposed as an essential concept to align science and innovation with society's needs, values, and expectations (Owen et al., 2012; von Schomberg, 2013). It seeks to create socio-economic, socio-ecological, and socio-ethical value through collective stewardship of innovation and entrepreneurial activities and address societal challenges sustainably and responsibly with increased societal impact (von Schomberg, 2011; European Commission, 2013; Stilgoe et al., 2013).

In principle, RI strives to ensure the inclusion of diverse stakeholders and the public in regional policies, innovation and entrepreneurial practices, the anticipation of their intended and unintended impacts on stakeholders and society, reflection on the underlying motivations, and responsiveness to stakeholders, users, and the public's concerns (Owen

et al., 2013 a; Stilgoe et al., 2013). Thus, the purpose is to govern regional policies and innovation and entrepreneurial practices in the production of optimally desirable outcomes which contribute directly to societal priorities (Frodeman, 2016) and broader societal impact (von Schomberg, 2013; De Grandis & Efstathiou, 2016).

Thus, the RI framework can be a viable approach to addressing grand societal challenges, considering its implications for regional policies, innovation, and entrepreneurial practices (Owen et al., 2013b; Stilgoe et al., 2013; von Schomberg, 2013, 2019). However, there are at least two critical issues to resolve in our understanding of RI.

Although RI has gained currency in recent years (Stilgoe & Guston, 2017), it remains a black box. There is no common understanding of what RI means (Owen et al., 2012; Oftedal, 2014; Burget et al., 2016; Owen et al., 2021b). Furthermore, RI as a concept is still evolving in different directions and remains largely normative (Timmermans & Stahl, 2014; Ribeiro et al., 2018). Few studies have examined RI, its purpose, and its implications for regions, firms in digital innovation, and entrepreneurship studies. Furthermore, there have been few empirical studies on practical approaches to demonstrating the challenges and opportunities of RI integration in innovation and entrepreneurship policies and practices (e.g. Asante et al., 2014; Flipse et al., 2014; Blok & Lemmens, 2015; Dreyer et al., 2017; Stahl et al., 2017; Auer & Jarmai, 2018; Martinuzzi et al., 2018).

Second, the concept is primarily driven by researchers and policymakers (Zwart et al., 2014; Burget et al., 2016; Owen & Pansera, 2019; Bernstein et al., 2022). They emphasise the conduct of responsible science and technological development, mainly failing to differentiate between invention and innovation (Pellé & Reber, 2015; Lubberink et al., 2017; Stahl et al., 2017; Long et al., 2020). Furthermore, the conceptualisation and operationalisation of responsibility in innovation, entrepreneurship, and regional development remain ambiguous (Forsberg et al., 2015; Fitjar et al., 2019) because most of the target actors-innovators, entrepreneurs, investors, funders, and firms are largely unaware of its purpose, implications, and outcomes (Blok & Lemmens, 2015; Stahl et al., 2017). Studies on RI in industry have highlighted the fact that RI concepts, tools, and methodologies are not aligned with industrial policy and practices (Blok & Lemmens, 2015; Scholten & Blok, 2015; Lubberink et al., 2017; Stahl et al., 2017). This lack of alignment makes it difficult for policymakers and firms to understand the overall purpose and practical significance of RI (Lubberink et al., 2019; Randle et al., 2012). Although academic research on RI of potential interest is increasing, relatively little is known about its impact on regional policy (e.g. Fitjar et al., 2019) and firm practices (e.g. Dreyer et al., 2017; Lubberink et al., 2017, 2019; Oftedal et al., 2019a).

In light of these critical issues, there is a need to understand the overall concept and purpose of RI and its implications for regional policies and innovation and entrepreneurial practices. Furthermore, there is a need to explore the operationalisation of RI in firms' innovation and

entrepreneurial processes for achieving sustainable and responsible outcomes. This thesis seeks to understand how the RI concept can be operationalised in regional policies and innovation and entrepreneurship practices. The main aim of this thesis is to investigate this application to regional innovation policy and firm innovation and entrepreneurial practices in the healthcare and welfare service sector. Therefore, the thesis seeks to address the following overarching research question:

'How does the RI approach facilitate regional policies and innovation and entrepreneurship practices in firms toward increased societal impact in healthcare and welfare services?'

This thesis addresses this overarching research question by exploring the concept of RI and its implications for regional policy, innovation, and entrepreneurship practices. The thesis explores the best practices for managing innovation to achieve desirable and responsible innovative solutions, building opportunity confidence for responsible venture creation, and synchronising between social and economic value creation in healthcare and the welfare service sector.

This thesis makes contributions to theory, policy, and practice. Overall, it makes a theoretical contribution by enriching the understanding of RI and its implications for regional policies, innovation, and entrepreneurship practices. It also contributes by exploring the approaches to integrating RI principles into innovation and entrepreneurial activities in managing innovation in firms and venture creation for a broader impact. At the practical level, the thesis adds

knowledge that firms can utilise to explore and exploit desirable and responsible solutions to complex problems and create socially responsible ventures for a broader impact. At the policy level, the thesis contributes by making policy recommendations that can help create synergies between healthcare and welfare policy and regional economic development policy.

1.2 Overview of the papers

The overarching research question of this thesis is addressed by four papers. The contents of the individual papers are summarised briefly here and in more detail in Chapter 5. The papers are provided in full in Part 2 of this thesis.

Paper I, *'Responsible Research and Innovation: A Systematic Review of the Literature and its Applications to Regional Studies*, focuses on Responsible innovation (RI) and regional policies and practices. It explores the concept of RI, its purpose, and the extent to which its applications to regional policies facilitate sustainable regional development. It shows that the essence of regional policies and practices is highly concentrated on regional competitiveness and economic growth, mainly overlooking the governance of innovation and entrepreneurship policies and practices. RI, however, focuses on the governance of policies and practices to address societal challenges with increased impact but lacks specificity. Therefore, the paper suggests that integrating RI into regional policies, including innovation and entrepreneurship policies and practices, can enable the achievement of

regional sustainable development goals. Furthermore, the purpose of regional policies, including innovation policies and practices, needs to be reflected and aligned with the processes and outcomes.

Paper II, *'Governing digital innovations for responsible outcomes– the case of digital healthcare and welfare services',* focuses on integrating RI into the innovation process in firms. The finding suggests that including diverse stakeholders and users in the innovation process enables need–solution interactions and optimal desirable solutions to societal challenges. Including RI in the early phase of the innovation process allows early need–solution interaction that enables risk and uncertainty management.

Paper III, *'Responsible innovation approach in venture creation and firm development: The case of digital innovation in healthcare and welfare services*', focuses on the integration of RI in entrepreneurship, specifically looking at RI in venture creation and firm development. The findings suggest that the RI approach in venture creation and firm development contributes to building opportunity confidence to create ventures and developing firms that contribute to addressing grand societal challenges.

Paper IV, *'Responsible Research and Innovation: Innovation initiatives for Positive Social Impact',* focuses on the RI approach in innovation and business development and the outcomes from such initiatives. The findings suggest that RI initiatives of business organisations can lead to sustainable business growth and have a positive impact on society.

Table 1: A brief overview of the research papers

RQ: How does the RI approach facilitate regional policies and innovation and entrepreneurship practices toward increased societal impact?			
Papers	Factors addressed	Theoretical Approaches	Methods
Paper I	Purpose • Responsible innovation • Regional policies	• RI • Regional studies	Systematic literature review
Paper II	Process • Integration of RI into innovation process	• RI • Innovation management	Multiple case studies
Paper III	Process • Integration of RI dimension in venture creation and firm development	• RI • Opportunity confidence • Venture creation	Multiple case studies
Paper IV	Outcomes • Sustainability • Social impact	• RI • Innovation and entrepreneurship • Social impact	A single case study

1.3 Outline of the thesis

This thesis comprises two parts. Part 1 has six chapters and presents the theoretical, methodological, and empirical foundations of the research conducted. Chapter 1 presents an introduction. Chapter 2 presents the research context. Chapter 3 addresses the theoretical background of the

study. Chapter 4 presents the methodology. A summary of the research papers is presented in Chapter 5. Chapter 6 presents findings, implications, limitations, avenues for future research, and concluding remarks. Part 2 of the thesis provides the research papers in full.

2 Context

2.1 Healthcare and welfare services

Providing healthcare and welfare services is one of the grand societal challenges. It is a complex challenge because it involves diverse interest groups: healthcare providers at different levels and organisations (hospitals, nursing homes, care centres, general practitioners, specialists),patients, governments and policymakers, insurance companies, municipalities, and innovators and entrepreneurs who provide new solutions (Iakovleva et al., 2019a). Providing healthcare and welfare services is also a complex challenge because it can be exacerbated by other, often interrelated grand societal challenges, such as pollution, demographic changes, lifestyle changes, and pandemics.

Addressing these issues is neither easy nor straightforward. Therefore, despite increased public spending on healthcare, governments and policymakers face extra pressure due to increasing public demand for adequate healthcare provisions (OECD, 2018). In response, governments and policymakers seek more innovation and entrepreneurial activities in this sector. However, a classic linear techno-scientific innovation approach might not work in such a context (Marschalek et al., 2022).

Furthermore, with the emergence of digitalisation, there is a growing belief that it could benefit the healthcare and welfare service sector. It could provide potential solutions to healthcare and welfare services (Bessant et al., 2017), provide quality service with ease of access at

reduced costs (Christensen et al., 2017; Yoo et al., 2012) and could bring entrepreneurial opportunities (Nambisan, 2017; von Briel et al., 2018). Therefore, digitalisation and digital innovation and entrepreneurship in the healthcare and welfare service sector are getting attention from governments, policymakers, businesses and the public (Greenstein et al., 2013; Huang et al., 2017).

Accordingly, governments and policymakers in European regions desire to harness synergy between two policy goals: healthcare and welfare policy and regional economic development policy (European Commission, 2010, 2011, 2016; Official Norwegian Reports, 2011). They are looking to develop new industries and businesses through an increasing ubiquity in the idea of care technology clusters as part of their regional innovation strategies (e.g. Asheim & Coenen, 2005; Asheim et al., 2011; Mazzarol, 2014). There is a growing assumption that it is easy to create and exploit the synergy between these two policy domains (Fitjar et al., 2019), but the question remains: how?

Furthermore, healthcare and welfare are sensitive and heavily regulated systems (Oftedal et al., 2019b). Related to the discourse on RI, public concerns about the underlying motivation for promoting digitalisation and digital technologies in this sector are growing (von Schomberg, 2011). Therefore, benefiting from the digitalisation of healthcare and welfare services will depend at least on how the purpose of regional policies and innovation and entrepreneurial activities are reflected and conducted (Bessant et al., 2017).

Different healthcare models are common worldwide, reflecting the necessity for responsible innovation in this sector. Therefore, this section briefly discusses these healthcare models followed by the Norwegian healthcare and welfare system, its anticipated challenges in providing responsible healthcare and welfare services, and initiatives from national and regional governments and policymakers in this direction. More specifically, it presents the Norwegian Smart Care Cluster (NSCC) (NSCC, 2020) as a cluster initiative (Asheim, 2004; Asheim et al., 2011) and its purpose. Finally, the section highlights the potential of digital innovation and entrepreneurship in healthcare and welfare services to meet the needs and expectations of stakeholders and users.

2.2 Healthcare models

Based on the source of their funding, four different healthcare models are common within industrialised nations, including the Beveridge model, the Bismarck model, the National Health Insurance or Tommy Douglas model, and the out-of-pocket model (Wallace, 2013).

The Beveridge model provides healthcare for all citizens and is financed by the government through tax payments. This model, developed by Sir William Beveridge in 1948 in the United Kingdom, has been adopted by most Scandinavian countries, Spain, New Zealand, Hong Kong, and Cuba, in addition to the United Kingdom. In this model, the patient does not have to pay any out-of-pocket fees, and all citizens are guaranteed

equal access to healthcare. Despite the accessibility to standardised benefits throughout the country, the main issues with this type of system are the tendency toward long waiting lists. Furthermore, over-utilisation of the system may lead to increased public spending on healthcare.

The Bismarck model uses an insurance system and is usually financed jointly by employers and employees through payroll deduction (Lameire et al., 1999). This model originated in Germany in the 19th century and is used in Germany, France, the Netherlands, Japan, Belgium, Switzerland, and some Latin American countries. This non-profit model includes all citizens (Wallace, 2013). This system was not initially established to provide universal health coverage; it focuses resources on those who can contribute financially. Although it involves a shift in mindset from healthcare as a privilege for the employed to a right for all citizens, the concern is how to provide care for those unable to work or afford contributions (Lameire et al., 1999). Furthermore, maintaining ageing populations with an uneven number of retired citizens compared to employed ones and how to remain competitive in healthcare provision are becoming pressing issues for such systems.

The National Health Insurance model incorporates elements of both the Beveridge and Bismarck models. This model uses private-sector providers, but payments are made by the government-run insurance programme, which is funded through a premium or tax on citizens. Founded in Canada, this model has been adopted by South Korea and

Taiwan in addition to Canada. Unlike American-style for-profit private insurance plans, this model tends to be less expensive and lower administrative costs (Lameire et al., 1999; Wallace, 2013). Since this model balances public insurance and private practices, hospitals can maintain independence while reducing internal complications with insurance policies. The model has low financial barriers to treatments, and patients are usually free to choose their healthcare providers (Viberg et al., 2013). The major concern with this model is long waiting lists for treatment. Patients with non-emergency procedures often face long waits to see physicians, which is a serious healthcare policy issue (Viberg et al., 2013). Furthermore, the long-term stability of this model is challenged by the overutilisation of healthcare resources by ageing populations and increasing healthcare service challenges (Lasser et al., 2006; Braveman et al., 2010).

The out-of-pocket model is found in most countries that are either too poor or too disorganised to provide any national healthcare system (Wallace, 2013). Healthcare is accessible to those who can afford it. The primary concern with this model is that disparities in wealth lead to inequalities in health outcomes (Lasser et al., 2006; Braveman et al., 2010).

No two healthcare systems are entirely alike, and none is entirely free from shortcomings. Furthermore, a one-size-fits-all approach does not function well in adopting a healthcare system. Therefore, what works in one country is not transferrable to another because of different health

concerns, priorities, expectations, and mindsets (WHO, 1996; Saltman et al., 1997). No matter what type of healthcare system a country has, the system should be fair and just to all citizens, not just the wealthiest (Lasser et al., 2006; Braveman et al., 2010). The common issues in all types of healthcare models are about providing affordable, equitable, quality, and sustainable healthcare provisions to citizens. Digital innovation is acknowledged to have the potential to address these issues by providing better quality at a lower cost. However, the solutions should meet the needs, values, and expectations of patients, healthcare providers, and other stakeholders in the regional innovation and entrepreneurship ecosystem. Responsible innovation can be vital in providing responsible and sustainable healthcare.

This thesis explores the understanding and application of RI in healthcare and welfare in the context of the Beveridge model used in Norway, which is the empirical setting of this thesis.

2.2 Norwegian Healthcare System

Healthcare in Norway is highly regulated through the national healthcare policy and falls under the Beveridge model. According to the stated goal of providing equal access to healthcare regardless of age, social status, or area of residence, the government is responsible for providing free public healthcare for all inhabitants, either wholly or partially, depending on its nature (Lindahl & Ringard, 2015; Official Norwegian Reports, 2011). In 2012, the Norwegian Coordination Reform was implemented with a significant motivation to promote healthcare provision and limit

public spending on healthcare provision (Official Norwegian Reports, 2009; Monkerud & Tjerbo, 2016). Healthcare in Norway is divided into two categories: primary and secondary (specialised). Almost all services are public and funded by the state or municipalities through taxes collected from citizens. Insurance companies play a minor role.

When it comes to innovation in healthcare in Norway, the complexity of this system and protective laws and regulations often serve as an 'institutional wall' for innovative firms trying to commercialise their products (Oftedal et al., 2019b). The government operates a control mechanism regarding the quality and quantity of services. A complicated procurement system is in place for the safety of medical solutions. This system is quite restrictive; only 'proved and tried' products can reach consumers. Although this system ensures safety, it is also quite restrictive in allowing innovative new solutions to find a pathway to the market. Firms that aim to work in this sector must deal with multiple actors driven by different motives. They must also ensure the legitimacy of their solutions to be able to enter the procurement system. Innovation in Norwegian healthcare has thus been called complicated and demanding (Oftedal et al., 2019b). At the same time, changing demographics increase public demand for quality care provision, and it is anticipated that current healthcare services will not be able to sustain the provision of healthcare and welfare in the near future (Iakovleva et al., 2019a). Thus, the Norwegian government has made some clear signals that digital innovations are in high demand in healthcare and welfare service sector.

The eHealth division was established under the Directorate of Health in 2003, which in 2016 was converted to a subordinate institute of the Ministry of Health and Care-The Norwegian Directorate of eHealth (NDE) (Doupi et al., 2010; NDE, 2020). The NDE is responsible for implementing the national policy on eHealth, establishing the requisite standards, and administrating the use of eHealth methodology nationwide.

2.3 Norwegian Smart Care Cluster

The Norwegian Smart Care Cluster (NSCC) was established in 2013. The cluster is located in the district of Rogaland and consists of more than 150 entrepreneurial firms, 50 municipalities, and government institutions as participants. The cluster was established as a part of the regional innovation strategies (e.g. Asheim, 2004; Mazzarol, 2014) to synchronise the healthcare and welfare policy and economic development policy by the regional policymakers and government.

Broadly, regional innovation strategies are an essential tool for facilitating collaboration and innovation within the regional innovation system (Asheim, 2004; Asheim et al., 2011). Specifically, the cluster aims to develop new industries and businesses by exploiting a related variety of advantages whereby non-medical technology opportunities are translated into the medical domain to meet the perceived needs of users and stakeholders (Asheim et al., 2011; Boschma et al., 2012). Therefore, NSCC provides a platform for creating a collaborative environment among firms, entrepreneurs, stakeholders, and users. It aims to exploit a

related variety of advantages seeking possible transformation of some oil technologies into healthcare and welfare technologies.

The nine start-up firms in our study all belong to the NSCC. The NSCC and all the case firms have an external orientation for broader impact and growth. Some of them already have collaborations and partnerships with firms at the international level.

2.4 Digitalisation of healthcare and welfare services

Despite the adoption of different healthcare models and increased public spending, healthcare and welfare policies and practices largely failed in narrowing down healthcare and welfare service disparity at the local, regional, and national levels (Batayeh et al., 2018; OECD, 2018). Furthermore, there are growing concerns and doubts about their ability to provide equitable, responsible, and sustainable healthcare and welfare (Marmot et al., 2012; Christensen et al., 2017). Therefore, innovative approaches are in immense demand (Christensen et al., 2017). Following the emerging discussion on digitalisation and information and communication technology (ICT), it is acknowledged that digital innovation in healthcare and welfare services could be a potential solution to addressing healthcare and welfare service issues (e.g. Hwang & Christensen, 2008; Liu et al., 2016). Digitalisation could be a powerful way to benefit stakeholders and users by increasing the ease of access to products and services whilst at the same time driving down the costs of provision (Yoo, 2010; Yoo et al., 2010; Yoo et al., 2012).

Furthermore, with the growing adaptability of digital technology, innovation and entrepreneurship are being intensified, raising both opportunities and challenges (Davidsson, 2003; Brynjolfsson, 2011; Davidsson, 2015; Lyytinen et al., 2016; Huang et al., 2017; Nambisan, 2017). For instance, with the growing digitalisation and adoption of digital technologies, several e-terms, such as e-commerce, e-learning, and eHealth, have recently flourished within the healthcare and welfare sector (Oh et al., 2005). According to European Commission, eHealth is defined as 'the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policymakers' (European Commission, 2016). Therefore, eHealth is emerging as a strategic move in the healthcare and welfare service sector (Doupi et al., 2010; Official Norwegian Reports, 2011; European Commission, 2016), opening up opportunities for new ventures within the healthcare and welfare service sector (Christensen & Raynor, 2003; Christensen et al., 2017; Fraussen & Halpin, 2018).

However, studies on digitalisation have mainly emphasised the potential benefits of digital innovation and entrepreneurship (Nambisan, 2017; Nambisan et al., 2017), opportunities for new ventures, new industries, and new economies (Yoo, 2010; Yoo et al., 2012; Porter & Heppelmann, 2014; Huang et al., 2017). Furthermore, the potential benefits of digital innovation and entrepreneurship in addressing healthcare issues have been receiving scholarly attention recently (e.g., Hwang & Christensen, 2008; Christensen et al., 2017). Accordingly, academic discussions on

adoption, issues on development and deployment of digital solutions are also emerging with growing attention on digitalisation (e.g. Hofmann, 2013; Liu et al., 2016; Nilsen et al., 2016).

Studies in eHealth have explored digital technologies as a tool to enable a process, function or service and as the embodiment of eHealth itself (Oh et al., 2005). However, most studies refer explicitly to the commercial aspects of eHealth (Oh et al., 2005; Kohlbacher & Hang, 2011), largely overlooking the potentially adverse effects of digitalisation in healthcare and welfare services. These previously overlooked issues must be addressed proactively to manage potential risks associated with these emerging technological innovations (Stahl, Jirotka et al., 2014; Jirotka et al., 2017; Lehoux et al., 2018). RI can be a viable approach to address the issues of negative impacts of digitalisation in healthcare and welfare services (Silva et al., 2021). More theoretical and empirical studies are deemed essential to explore the mechanisms of responsible development and deployment of digital technologies to harness the potential of digital innovation and entrepreneurship and to achieve overall healthcare and welfare goals.

3 Theoretical Framework

3.1 Introduction

This thesis explores the concept of Responsible innovation (RI) and its implications for regional policies and firm practices. This chapter presents RI and its dimensions of inclusion, anticipation, reflexivity and responsiveness in section 3.2. The chapter continues with the integration of RI in innovation and entrepreneurship purpose, process, and outcomes, followed by a conceptual framework in section 3.3. The chapter then ends with a summary.

3.2 Responsible Innovation (RI)

Responsible innovation (RI) has emerged as an ambitious and forward-looking concept to address the topics of public concerns and govern research, innovation and entrepreneurial trajectories towards socio-economic, socio-ethical and socioecological benefits (von Schomberg, 2011; Owen et al., 2012; Stahl, 2012; Stilgoe et al., 2013). RI aims at incorporating responsibility into research, innovation and entrepreneurial activities (Flick, 2016) through democratic governance of the purpose of research and innovation and their orientation towards the 'right impact' (Stilgoe et al., 2013).

Although RI is an emerging field in the European research and innovation policy context (European Commission, 2011), it is spreading

in different directions and beyond the EU (Owen et al., 2012; Fisher & Rip, 2013; Bernstein et al., 2021). Whilst RI may be a relatively new and quickly spreading line of investigation, the area of scientific concern about the social impact of science and technology is not new and has been there since the late 1940s (Silva et al., 2018; Stilgoe &Guston, 2017).

Hence, the root of RI can be traced back decades (Grunwald, 2011; Armstrong et al., 2012; Owen et al., 2012; von Schomberg, 2013; Owen & Pansera, 2019). Furthermore, responsibility has always been an essential theme of research and innovation practices (Owen et al., 2021a; Stilgoe et al., 2013; Stilgoe & Guston, 2017). RI expands concepts and theoretical approaches previously used in scientific inquiries into the responsibility in research and innovation by drawing on science and technology studies (STS) (Forsberg et al., 2015; Griffy-Brown et al., 2018). The technology assessment (TA) movement during the 1970s, beginning in the US as a science-based and policy-advising activity (Grunwald, 2011), during the 1980s equivocally advocated 'shaping of technology' according to societal needs and values (Bijker et al., 2012) and scholar later developed constructive technology assessment (CTA) (Rip et al., 1995; Schot & Rip, 1997). These developments and the emergence of ethical, legal and social implications/aspects (ELSI/ELSA) (Forsberg, 2015) during the 1990s, as well as ethics and philosophy of technology (Chadwick & Zwart, 2013; Zwart et al., 2014; Forsberg, 2015) all, may be seen as roots of RI (Grunwald, 2011; Owen et al., 2012;

Owen & Pansera, 2019). Thus, it can be concluded that the term RI has been built on complementary scholarly contributions (Owen et al., 2012; Owen et al., 2021a; Owen & Pansera, 2019). While this stands, it may suggest that the concept of RI is 'old wine in new bottles.' However, what makes RI distinct is its emphasises on the consideration of social and ethical issues at the design phase of the innovation process itself and not only after a product or service has been developed and launched (Owen et al., 2013a; Stahl et al., 2017; Owen & Pansera, 2019). Therefore, the main purpose of RI is to govern science, innovation and entrepreneurial activities from the very early stage and to direct them towards the right impact (Stahl, 2022; von Schomberg, 2013; von Schomberg, 2019; von Schomberg & Hankins, 2019b) and contribute to addressing societal challenges.

RI, according to von Schomberg, is defined as 'a transparent interactive process by which societal actors and innovators become mutually responsive to each other with a view to the ethical acceptability, sustainability and societal desirability of the innovation process and its marketable products (to allow a proper embedding of scientific and technological advances in our society)' (von Schomberg, 2011, p. 9). Although this is the most cited definition, many other definitions exist (e.g. Sutcliffe, 2011; von Schomberg, 2011, 2013; Owen et al., 2013a; Stahl, 2013; Stilgoe et al., 2013; Wickson & Carew, 2014). On the one hand, the responsible innovation movement still needs to exercise more on developing a common understanding and definition of responsible

innovation (Owen et al., 2021a). On the other hand, it has the challenge of demarking itself from the already existing complementary approaches and practices (Dreyer et al., 2017; van de Poel et al., 2020).

At the current state, it is still uncertain whether RI emerges as a genuinely transformative and even novel approach to governing science and innovation (Owen et al., 2012a; Owen et al., 2021b). A further challenge is finding what might involve practice and ways to motivate to adopt and implement the RI framework in innovation and entrepreneurial activities (Bessant et al., 2019; Lubberink et al., 2017, 2019; van de Poel et al., 2020). Even though the RI approaches seem challenging and uncomfortable, the widening grand societal challenges make it even more critical than ever (Owen et al., 2013b; Owen et al., 2021a; Stilgoe & Guston, 2017). Following RI discourse, the RI approach in innovation and entrepreneurial activities could lead to desirable, responsible and sustainable solutions to address socioeconomic, socio-ethical and socioecological issues (Owen et al., 2013a; von Schomberg, 2019; von Schomberg & Hankins, 2019a).

With this, RI aims to govern innovations and entrepreneurial ventures vital in addressing societal and ecological issues for a sustainable future. These ambitious goals of RI can only be achieved if research and innovation institutions, especially the entrepreneurs and industrial actors, adopt and practice RI in their corporate activities (Blok & Lemmens, 2015; Lubberink et al., 2019; Owen et al., 2021a; Stahl et al., 2017).

Literature reviews indicated that RI discussion took place primarily at the policy level (Loureiro & Conceição, 2019; Schuijff & Dijkstra, 2020), and they were limited to research projects funded by public funding bodies (Bernstein et al., 2022; Novitzky et al., 2020; Thapa et al. 2019). Despite the growing interest and studies on RI in the industry in recent years, the ambiguity regarding RI integration in innovation and entrepreneurship at the firm level still exists (Lubberink et al., 2017; Owen et al., 2021a; Stahl, 2022; Stahl et al., 2017). RI studies in the industry suggested challenges and opportunities for integrating RI in innovation and corporate activities (e.g. Blok & Lemmens, 2015; Long et al., 2020; Lubberink et al., 2017, 2019; Martinuzzi et al., 2018). According to these scholars, there is a need to find simple, clear and credible guidelines for implementing RI in the innovation and entrepreneurship processes rather than reinventing wheels (Dreyer et al., 2017; Long & Blok, 2018). Furthermore, scholars meant that firms and entrepreneurs should see the benefits of adopting and practising RI in innovation and corporate activities (Auer & Jarmai, 2018; Lubberink et al., 2019; Martinuzzi et al., 2018; van de Poel et al., 2020).

In 2013, Stilgoe and colleagues advanced the procedural approach to RI comprised of four principle dimensions: inclusion, anticipation, reflectivity and responsiveness (Stilgoe et al., 2013). This approach can facilitate firms in innovation and entrepreneurship governance for societal problem solving. Furthermore, these RI dimensions provide

tools that are useful for understanding the purpose, process and outcomes of regional policies, innovation and entrepreneurship policies and practices in an iterative process.

3.2.1 Inclusion

Inclusion refers to engaging a broader group of stakeholders and the public from early in decisions about innovation and entrepreneurial activities throughout the entire process. It means opening up a platform for interaction, discussion and dialogue for mutual learning, increasing transparency and understanding in innovation and entrepreneurial process, and consensus-building for societal problem alleviation (Irwin, 2006; Hajer, 2009; Concannon et al., 2014; Kok et al., 2016). Including a diversity of stakeholders and users in the innovation and entrepreneurship activities, firms and entrepreneurs can intimately understand their actual needs, values, concerns and expectations (Marschalek et al., 2022; von Schomberg, 2011). Inclusive firms are advantaged with access to knowledge diversity (Carayannis & Campbell, 2014; Solheim, 2016), opinions, perspectives and critical views, which could be essential for cocreating innovation and entrepreneurial opportunities (Sanders & Stappers, 2008; Hoyer et al., 2010).

In addition to the opportunities for a diverse knowledge base, the inclusion of users or consumers could be an enabler of creative and constructive problem-solving platforms opening up to new insights and alternatives innovations (Oliveira et al., 2019; von Hippel, 2001, 2005;

von Hippel & von Krogh, 2015), individual as well as collective intelligence (Fitzgerald et al., 2016) and transfer of tacit knowledge (Marschalek et al., 2022; Reagans & McEvily, 2003; Timmermans et al., 2020) to find solutions for grand societal challenges. Overall, stakeholder engagement in innovation and entrepreneurship activities enhances positive changes to the quality and impact of innovation and entrepreneurial intentions (Cottrell, Whitlock et al. 2015, Likumahuwa-Ackman, Angier et al. 2015).

Goodman and Sanders Thompson (2017) classified a broad spectrum of stakeholder engagement primarily within three broad categories as non-participation, symbolic participation, and engaged participation. The usual purpose of non-participation engagement is not to engage stakeholders in planning, implementation, evaluation, and decision-making. It is not a genuine stakeholder engagement. The purpose of this type of engagement is limited to outreach or education. In the symbolic participation category, stakeholders are allowed to hear plans and have a voice, but it is not sure whether their voices are heard or carry weight, and there will be changes in the status quo. Therefore, in this category of stakeholder engagement, stakeholders are not meaningfully engaged, which includes shared decision-making. The purpose of this type of engagement is focused on coordination and cooperation. Finally, in the engaged participation category, stakeholders, including users and advocacy groups that traditionally have limited power, are allowed shared decision-making authority with powerful, influential stakeholders. In this type of engagement, stakeholders collectively

manage the project on stakeholder priorities (Arnstein, 1969). Furthermore, upstream stakeholder engagement from the design phase of innovation and entrepreneurship policies and practices can facilitate anticipation of risk downstream (Blok, 2022; Blok et al., 2018). Thus, it may contribute to the production of sustainable and responsible products and services which are desirable and acceptable (Blok, 2020).

Despite the benefits of inclusion, research has indicated several challenges to inclusion (Blok et al., 2022; Long & Blok, 2018; Lubberink et al., 2017; van de Poel et al., 2020). Therefore, they need to be addressed for the full potential benefits through inclusion in research, innovation and entrepreneurial activities. For instance, the most common challenges reported were that stakeholder engagement is time and resource-consuming (Reed, 2008; Concannon et al., 2014; Blok et al., 2015; Thapa & Iakovleva, 2023), difficulty establishing stakeholder representativeness throughout the course of the project, stakeholder distress while participating and overcoming cultural differences among participants (Reed 2008, Concannon, Fuster et al. 2014, Esmail et al. 2015), balancing competing interests, addressing implicit power differentials, and managing conflicts (Brand & Blok, 2019; Concannon et al., 2014).

Minoja et al. (2010) indicated that stakeholder engagement could turn into stakeholder cohesion which may have a ‘dark side’ to the extent that it results in inertia and resistance to change, thus reducing the propensity to innovation and change. Furthermore, if not managed well, there is a danger that stakeholder engagement might result in engagement fatigue

(Reed 2008) and 'talking shop', which might create a situation of ambiguity and subsequently delay in decision-making (Vedwan et al., 2008). Importantly, for effective stakeholder engagement, there should be a commitment from firms, stakeholders, and policymakers to invest time and resources for training and support from the beginning of the innovation and entrepreneurship project and throughout the entire lifecycle of the project (Esmail et al., 2015; Goodman & Sanders Thompson, 2017; Lavery, 2018).

3.2.2 Anticipation

Anticipation refers to systematic thinking about intended and unintended consequences that decisions, innovation, and entrepreneurial activities could cause in society (Guston, 2006, 2014). 'Anticipation is more about practising, rehearsing, or exercising a capacity logically, spatially, or temporally prior than it is about divining a future' (Guston, 2014, p. 226). Firms, policymakers, innovators, and entrepreneurs need to consider anticipation of the consequences, effectiveness, and alternatives to decisions about solutions given grand societal challenges. The purpose of anticipation in innovation and entrepreneurial trajectory is not about producing blueprints but instead opening up for opportunities, alternatives and diverse pathways to co-create innovation and entrepreneurial decisions (Martin, 2010; Gudowsky & Peissl, 2016; Owen et al., 2021b) aiming at societal impact (Rhisiart et al., 2017).

Unlike traditional forecasting, anticipation is not a set of techniques based on assumptions and expectations of translating input into outputs

predicting the future; rather, it is a process of collective search and learning and co-creating a sustainable future (Martin & Irvine, 1989; Ferdig, 2007; von Schomberg, 2013; Markus & Mentzer, 2014).

There is a growing consensus among scholars and policymakers on the need to improve foresight in issues of science, technology, innovation and entrepreneurship (Martin, 2010; Ozdemir et al., 2011; Gudowsky & Peissl, 2016; Rhisiart et al., 2017). In the same vein, STS scholars have contributed to advancing some guidance on the process that facilitates anticipation (Stilgoe et al., 2013; Schot & Steinmueller, 2018). Constructive technology assessment (Rip et al., 1995) and upstream public engagement (Wilsdon & Willis, 2004) are developments within the anticipation of a possible and desirable future. Several methods, such as technology assessment, foresight, and horizon scanning, could facilitate anticipation (Thapa et al., 2019). However, they are used narrowly, and they are likely to exacerbate technological determinism, like the technology forecasting approach (Stilgoe et al., 2013).

3.2.3 Reflexivity

Reflexivity in RI means 'holding a mirror up to one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held' (Stilgoe et al., 2013, p. 1571). It refers to second-order reflexivity, reflexive not only to the insiders within organisations but also to the external stakeholders. Innovators and entrepreneurs should prioritise second-order reflexivity to scrutinise how their underlying

value system shapes research, innovation, and entrepreneurial activities (Schuurbiers, 2011; Stilgoe et al., 2013).

However, this has not been to suggest that innovators and entrepreneurs do not reflect aloud and amongst themselves (Waterton et al., 2001; Fisher et al., 2006). They are continuously reflexive, but in a way that is mainly restricted to across their networks, rather than focusing on users, secondary stakeholders, or public enterprises, namely, first-order reflexivity (Fisher et al., 2006; Schuurbiers, 2011; Wynne, 2006, 2011). Furthermore, firms, innovation, and entrepreneurship actors ought to concentrate on second-order reflexivity to contribute and gain benefits from innovation and entrepreneurship in the context of grand challenges (Schuurbiers, 2011; Stilgoe et al., 2013).

Reflexivity is essential to assess preconceptions critically and pay close attention to value systems and social practices in innovation and entrepreneurial processes (Owen et al., 2013a; Wynne, 2011). Reflexivity enables the true value proposition and makes it possible to stick to the commitments and expectations made (Knoblauch, 2014). Indeed, it enables trustworthy innovation and entrepreneurship policies and practices for societal transformation (Owen et al., 2013a). The significance of reflexivity for innovation and organisational productivity and growth is a well-discussed topic (e.g. West, 2000; Tjosvold et al., 2004). As such, team building for productivity, creativity for innovation, and trustworthiness for the brand image are strategic interests of policies and organisational growth (Weber & Rohracher, 2012; Weber et al.,

2016). However, the limited reflexivity within their own networks and interest groups indicates that firms and entrepreneurs are primarily engaged in first-order reflexivity (Owen et al., 2021a; Stilgoe et al., 2013).

As such, the prevalent first-order reflexivity limits innovation and entrepreneurship actors from self-questioning and learning about the priority of one innovative alternative option over others (Wynne, 2011), locking into the dominant design of solutions too early in the innovation and entrepreneurship process. Furthermore, it restricts them from challenging the more entrenched organisational cultural habits (Jasanoff, 1990,2006), leading to 'lock in' or path dependency (David, 2001; Liebowitz & Margolis, 1995). The second-order reflexivity (Schuurbiers, 2011) enables innovation and entrepreneurship actors, as well as the stakeholders in the innovation and entrepreneurship ecosystem, to open up to diverse and even conflicting perspectives to maintain transparency in science, technology, innovation, and entrepreneurship (Jasanoff, 2006; Fisher, 2007; Wynne, 2011).

Thus, second-order reflexivity facilitates creating trustworthiness among firms, stakeholders, users and the public in the innovation and entrepreneurship ecosystem (Wynne, 2006), establishing mutual responsibility to take care of the future (Stilgoe et al., 2013; von Schomberg, 2013; Groot et al., 2019).

Therefore, reflexivity creates and strengthens platforms for collaboration and co-creation with users and stakeholders centric, innovative solutions

benefiting firms, stakeholders and society at large (Weber & Rohracher, 2012). It is imperative to improve the transparency of the innovation and entrepreneurship process through reflexivity. This is because if stakeholders and users understand and can articulate the innovative products or services, their perceived trust will increase (Meijboom et al., 2006; Asveld, 2016; Kuester et al., 2018), and they are far more likely to adopt the solutions and assist in the diffusion of innovation (Concannon et al., 2014). Furthermore, it opens up opportunities for collaboration and building a reputation in society (Blok, 2022; Lee & Kim, 1999; Stahl, 2013), which is a vital strategy for sustainable business development and growth. Failing to reflect on how they create, deliver and capture values to stakeholders and users, however, can be counterproductive. They should be mindful of the value proposition. An exaggerated value proposition heightens expectations among users and stakeholders. Failing to meet their expectations raises trust issues which might negatively affect business development and growth in the long run (Coeckelbergh et al., 2016).

3.2.4 Responsiveness

Responsiveness, according to Pellizzoni, ‘refers to a situation where there is neither presumption of sufficient knowledge and control nor reliance on ex-post accounts and adjustment of self-established courses of action, but rather a receptive attitude to external inputs to help in deciding what to do’ (Pellizzoni, 2004, p. 557).

Responsiveness in innovation and entrepreneurial activities implies that firms and policymakers must listen carefully to critical feedback and respond proactively. Such responsive nature would ensure their respect and care towards users, stakeholders, and the public in innovation and entrepreneurship policies and practices (Meijboom et al., 2006). It also opens up access to constructive ideas or verifies creative novel ideas for potential innovation, business creation, and policy framing through constant interaction, reflection, and responsiveness (Owen et al., 2013a; Stilgoe et al., 2013).

Pellizzoni (2004) argues that responsiveness is a neglected dimension of responsibility, and though scholars have extensively discussed it, they often fail to distinguish between two very different meanings of responsiveness, namely, reaction and response. Conversely, the responsiveness equivalent to reaction is the logic of the immune system in the body, which corresponds to the ability of every organism and social organization to respond to stimuli to adapt and survive in a changing environment. The other responsiveness equivalent to response entails the previous listening to a question (Pellizzoni, 2004). In addition, it entails reflexivity in the search for a possible terrain for sharing (Pellizzoni, 2004; Callon & Lacoste, 2011; Schuurbiers, 2011; Wynne, 2011). Furthermore, it necessitates responding to new knowledge, perspectives, views, concerns and norms, which prompt research, innovation and entrepreneurship decisions and activities (Schuurbiers, 2011; Owen et al., 2013a). Importantly, it calls for institutionalised response and co-responsibility among the actors in innovation and

entrepreneurial ecosystem (Callon & Lacoste, 2011; Stilgoe et al., 2013; von Schomberg, 2013; Wickson & Carew, 2014; Owen et al., 2021a; Stahl, 2022).

Responsiveness in innovation and entrepreneurship management is widely viewed as equivalent to a reaction to adapt and survive. Firms will die no matter how resourceful they are if they fail to change with changing circumstances (Tidd & Bessant, 2016). How firms survive in the face of dynamic change (e.g. Nelson & Winter, 1982; Hannan & Freeman, 1984; Christensen, 1997), competitive advantage (Porter, 1980), a resourced-based view of the firm (Barney, 1991), and dynamic capabilities (Teece et al., 1997; Eisenhardt & Martin, 2000) is studied extensively with respect to organizational change and adaptation. Furthermore, the ability of firms to overcome inertia and path dependencies is viewed as the core of dynamic capability essential for competitive advantage to adapt, survive and grow (Eisenhardt & Martin, 2000; Zott, 2003; O'Reilly & Tushman, 2004; Teece, 2007).

However, with the changing relationship between science and society (Sturgis & Allum, 2004), knowledge production (Gibbons et al., 1994; Nowotny et al., 2003), globalization (Lundvall, 2010), and the increasing complexity of grand challenges (Von Schomberg, 2007), responsiveness equivalent to reaction alone will not be the best alternative for organisations to build the dynamic capability necessary to adapt and survive. A shift is needed towards responsiveness to include engaged pluralism through interdisciplinary (Fagerberg et al., 2013; Rosenman et

al., 2020) or even transdisciplinary approaches in managing innovation and entrepreneurship processes (Wickson & Carew, 2014).

Successful integration of RI in innovation and entrepreneurship to result in the 'right impact' requires the firms, entrepreneurs and policymakers to adapt and practice RI in their innovation and entrepreneurial policies and practices' purpose, process and outcomes (Fitjar et al., 2019; Jirotka et al., 2017; Stahl et al., 2017; Stilgoe et al., 2013). Whether RI principles can facilitate reflecting the purpose, process, and outcomes of innovation and entrepreneurship policies and practices is ambiguous and warrants further exploration.

3.3 Integration of RI in innovation and entrepreneurial activities

In view of the need for collective stewardship of science, technology, innovation and entrepreneurship (Stilgoe et al., 2013) and the need for engaged pluralism through interdisciplinary studies (Fagerberg et al., 2013; Rosenman et al., 2020) in the context of grand societal challenges, there is a need for interaction of RI with regional policies and, innovation and entrepreneurship policies and practices (Owen et al., 2021b).

Innovation is widely recognised as a significant determinant of economic growth, employment, and global competitiveness at regional, national or global levels (Asheim et al., 2011; Lundvall et al., 2011; Boschma et al., 2012; Fagerberg et al., 2013; Edquist, 2014). It is widely accepted as a vitally important social and economic phenomenon (Fagerberg et al.,

2013) which bears the potential to provide solutions to socio-economic and socio-ecological challenges (Dosi, 2013; Fagerberg et al., 2013; Owen et al., 2013b; von Schomberg & Hankins, 2019a). Similarly, at firm level, innovation is widely recognised as a mechanism for competitiveness (Teece et al., 1997; Lavie, 2006; Teece, 2007) and is consistently one of the most important characteristics associated with firms' success (Kline & Rosenberg, 1986; Klomp & Van Leeuwen, 2001; Teece, 2007; Christensen et al., 2008; Lazonick et al., 2013). Hence, the need for innovation is imperative (Tidd & Bessant, 2016). However, not all innovations are necessarily good for society (Soete, 2019); many cannot fulfil their promises and even cause harm to society and the environment (Owen et al., 2013b; Soete, 2013; von Schomberg, 2019; von Schomberg & Hankins, 2019a). Therefore, innovation success does not lie simply in the number of products or services launched as innovation outputs but also in the impact it creates on socioeconomic, socio-ethical and socioecological values in addressing the grand societal challenges (European Commission, 2014a, 2014b; Timmermans et al., 2017; Timmermans & Stahl, 2014).

In this study, successful innovation is defined as the creation and implementation of new processes, products, services, and business models which result in significant improvements in outcomes, efficiency, effectiveness, or quality (Albury, 2005, p. 51). Thus, innovation is not just an idea but also its development and

implementation (Tidd & Bessant, 2016), which should address societal challenges and create a positive impact.

Similarly, it is acknowledged that entrepreneurship is an engine that stimulates economic development, employment, and superior profit (Schumpeter, 1934; Gartner, 1989; Shane & Venkataraman, 2000; Davidsson, 2003; McMullen & Dimov, 2013). The thesis considers entrepreneurship to be a process for identifying, evaluating, and exploiting opportunities in creating entirely new firms or entrepreneurial business units within existing organisations (Aldrich, 1999; Alvarez & Barney, 2004; Acs & Audretsch, 2005). Entrepreneurship as a process ultimately aims at new venture creation (e.g. Bhave, 1994; Katz & Gartner, 1988). It begins with venture ideas, evaluation, and exploitation of opportunities to introduce novel products or services that creates value (Shane & Venkataraman, 2000).

Entrepreneurs discover opportunities and translate them into successful venture creation for growth and profitability (Stevenson et al., 1994; Shane & Venkataraman, 2000; Shane, 2004; Grégoire & Shepherd, 2012). However, 'opportunities' presented and discussed within entrepreneurship research may not provide a concrete explanation (Alvarez & Barney, 2007; Klein, 2008; Davidsson, 2015) and could even be elusive in the context of grand societal challenges (Hsieh et al., 2007; Davidsson, 2015).

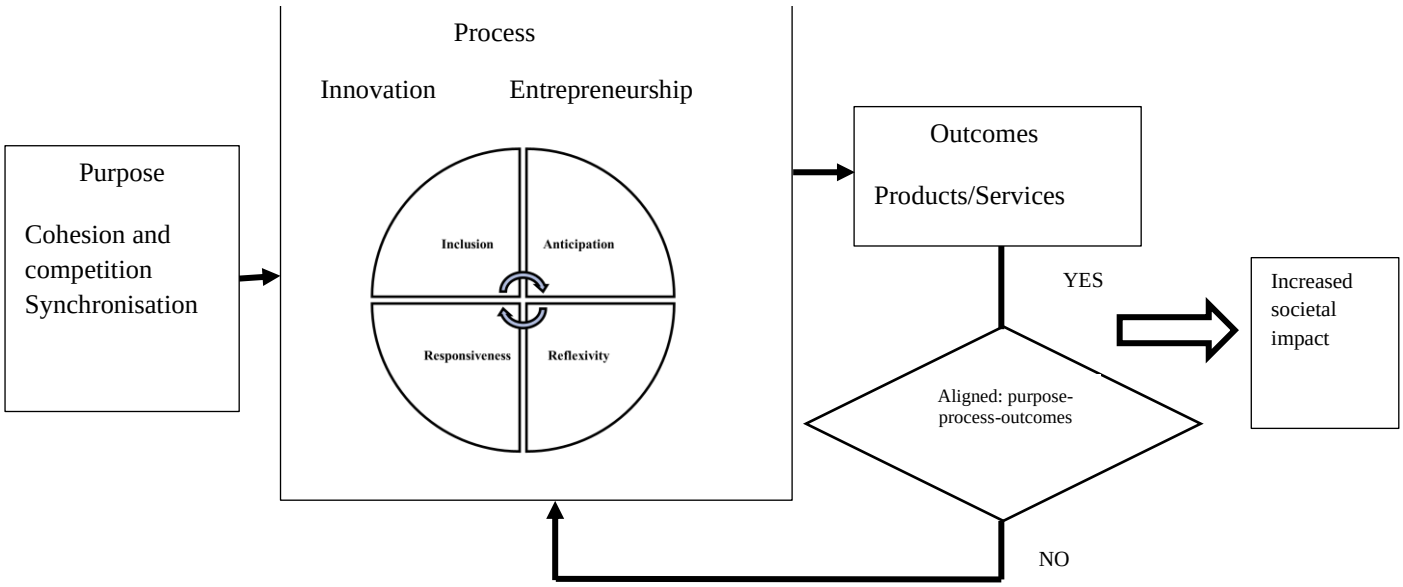
Therefore, there is a need to understand how individuals and teams, as well as other economic actors such as regional policymakers, explore and

exploit opportunities, their purposes, processes, and outcomes for innovation and entrepreneurship. This thesis, therefore, looks at both individuals and firms at different development stages – startups, market-launched, and established firms – and goes further to consider how these individuals and firms are embedded within a regional context.

Accordingly, governing regional policies and innovation and entrepreneurship policies and practices in a manner that alleviates grand challenges and increases positive social impact, the purpose (why), the process (how), and the outcomes (what) of innovation and entrepreneurship policies and practices need to be aligned and reflected continuously (Stilgoe et al., 2013; Jirotka et al., 2017; Stahl et al., 2017). Integrating RI in the purpose, process and outcomes of regional policies and innovation and entrepreneurship practices can facilitate responsible and sustainable solutions to regional challenges with increased impact (Jirotka et al., 2017; Owen et al., 2013a; Stilgoe et al., 2013).

Broadly, the understanding and practice of RI in innovation and entrepreneurship can be synthesised and consolidated into three main themes: purpose, process and outcomes of innovation and entrepreneurship policies and practices, as articulated by Stilgoe et al. (2013), Jirkota et al. (2017), Stahl et al. (2018), Iakovleva et al. (2019b) and Fitjar et al. (2019) and illustrated in Figure 1 below.

Figure 1: Theoretical Framework- RI integration in regional policies and innovation and entrepreneurship process



Based on Figure 1, the central argument is that the RI can facilitate decisions about regional policies, innovation and entrepreneurship policies and practices, their purpose, process and outcomes. Therefore, the thesis looks at the overall purpose of regional policy and digital innovation and entrepreneurship. On process, it looks at innovation and entrepreneurial processes. Finally, on outcomes, it focuses on the impact of innovation and entrepreneurial activities in the regional healthcare and welfare sector context.

In subsequent sections, this thesis explores viable approaches to integrating RI in the purpose, process, and outcomes of regional policies,

innovation, and entrepreneurial activities. The chapter concludes with a summary of the theoretical framework in section 3.4.

3.3.1 Purpose

Several decades of innovation and entrepreneurship research, policies, and practices have not only contributed to the production of knowledge, human well-being, and socioeconomic transformation of society but also created unintended consequences and negative externalities (Owen et al., 2012; Soete, 2013; Martin, 2016; Owen & Pansera, 2019). The growing disparity in and between regions (e.g. Rodríguez-Pose, 2018; Storper, 2018), the financial crisis of 2008 (e.g. Muniesa & Lenglet, 2013), climate change (e.g. Change, 2001), and the growing dysfunctional effects of entrepreneurship in society (Zahra & Wright, 2016) are some of the examples of unintended and even undesirable impacts associated with innovation and entrepreneurial activities.

These raise concerns about whether all policy decisions and innovation and entrepreneurial activities favour society (Nicholls, 2009; Soete, 2013; Martin, 2016; Zahra & Wright, 2016; Soete, 2019) and questions about their purpose and underlying motivations (Owen et al., 2013a; von Schomberg, 2019). These concerns come from the public, civil society and stakeholders in the regional ecosystem (Fagerberg et al., 2013; European Commission, 2014a; Martin, 2016). Thus the public discourse is often critical of innovation and entrepreneurship policies and practices, which are believed to prioritise economic growth over and above the

needs, interests and expectations of stakeholders, users, and the public in the regional ecosystem (Owen et al., 2021a; von Schomberg, 2019). Such discourse creates tensions for governments and policymakers who need economic growth in the regions and firms whose survival depends on profitability (Stahl et al., 2017).

However, RI aims to maximise the socioeconomic, socio-ethical and socioecological values and broader societal impact through science and innovation beyond economic value creation (Owen et al., 2021a; Thapa & Iakovleva, 2023; Voegtlin et al., 2022; von Schomberg, 2019). Therefore, RI emphasises the reflection on the purpose and underlying motivation of particular innovation and entrepreneurial policies and practices under consideration (Owen et al., 2013a; Stilgoe et al., 2013; Jirotka et al., 2017) (not only the process and products of innovation and entrepreneurship (Stilgoe, 2011)).

Accordingly, in the realm of grand societal challenges, the primary purpose of science, innovation and entrepreneurship policies and practices should favour the production and promotion of innovative solutions that are socially desirable and acceptable (Bacq & Aguilera, 2022; von Schomberg & Blok, 2021). The purpose and motivation should be driven by a desire to take actions that will benefit society (Owen et al., 2013b; Owen et al., 2021b; von Schomberg & Hankins, 2019a). Therefore, the priority should be on the alignment of innovation and entrepreneurship and the policies that drive them with regional

needs, values and expectations (Fitjar et al., 2019; Jakobsen et al., 2019; Thapa et al., 2019; von Schomberg, 2019).

Furthermore, actions caused by purpose are guided normally by consciously held choices and goals (Locke, 1996), which can be introspectively reported and analysed (Yitshaki & Kropp, 2016). Furthermore, motivation to accomplish goals is defined by the link between intentions and actions (Baron, 2012). Purpose and motivation shape the action (Locke, 1996; Baron et al., 2012; McGurk & Baron, 2012). Therefore the impact of the perceived purpose of policies, innovation and entrepreneurship should not be underestimated; rather, they should be reflexive to the stakeholders in the innovation and entrepreneurship ecosystem (Stahl, 2022; Stahl et al., 2017).

Most RI literature so far has focused mainly more detail on the process and products and services as outcomes overlooking the purpose and the underlying motivation of innovation and entrepreneurial activities (e.g. Asante et al., 2014; Bernstein et al., 2022; Gonzales-Gemio et al., 2020; Gurzawska, 2021; Tabarés et al., 2022). Although the literature focuses more on processes and products as outcomes, the purpose of innovation and entrepreneurship policies and practices should be considered (Jirotka et al., 2017; Stahl et al., 2017; Stilgoe, 2011) for broader societal impact. Following RI discourses can be a viable approach in shaping the purpose of innovation and entrepreneurial policies and activities to achieve regional goals of addressing grand societal challenges. However, whether and how RI can be brought into practice remains ambiguous.

Therefore, there is a need to explore why and how regional policymakers, firms and entrepreneurs prioritize innovation and entrepreneurial ventures, which are guided by the stakeholders' needs, values, and expectations in the regional ecosystem.

3.3.2 Process

The next crucial step to realise the perceived purpose is the activities undertaken in pursuing innovation and entrepreneurship policies and practices. With the changing relationship between science and society (Sturgis & Allum, 2004), new modes of knowledge production (Gibbons et al., 1994; Nowotny et al., 2003), and perceived risk of rapidly emerging novel technologies, including digital technologies (Hellström, 2003; von Schomberg, 2007) necessitate reconsideration about a common understanding of shared values, responsibilities and better address the widening grand societal challenges. Furthermore, in modern society, it has become more apparent that innovation and entrepreneurial activities must be aligned with societal needs, values and expectations (Owen et al., 2012; Bessant, 2013; von Schomberg, 2013; Stilgoe & Guston, 2017). Hence, ethical, legal and social issues that might result from innovation and entrepreneurial activities should be addressed early on and assessed by the inclusion of stakeholders and citizens (Taebi et al., 2014; Hester et al., 2015).

Failing to address the concerns of stakeholders, users, and citizens in innovation and related activities might meet societal resistance to

adopting and diffusion of such innovative solutions despite bearing the potential of socioeconomic transformation (Asveld et al., 2015). Furthermore, such failure would worsen public confidence in science, technology, innovation and entrepreneurship, further deteriorating public trust in firms and associates (O'Doherty, 2022; Sjöberg, 2001).

Decades of research and practice of innovation and entrepreneurship have contributed to the theoretical advancement of these fields. Various process models for innovation management (e.g. Cooper, 1990; Tidd & Bessant, 2016) and venture creation (e.g. Bhave, 1994; Katz & Gartner, 1988; Bakker & Shepherd, 2017) enabled firms to manage firm-level innovation for competitiveness and exploiting opportunities for successful venture creation for profitability and organisational growth. However, with changing innovation and entrepreneurial landscapes, competitiveness and opportunities, RI suggest that firms and entrepreneurs consider previously overlooked negative externalities and societal issues while managing innovation and entrepreneurship. Either in the innovation process or in the venture creation process, various issues associated with the ethics, dilemmas and impact can be anticipated by the inclusion of stakeholders, users and the public from the beginning of the process, continually reflecting and responding throughout (Stilgoe et al., 2013; von Schomberg, 2013; Taebi et al., 2014). The argument here is that integrating the principle dimension of responsible innovation, inclusion, anticipation, reflexivity and responsiveness in the innovation process model from the design phase onwards enables firms to mitigate risks and manage the uncertainty associated with users' and

stakeholders' concerns, needs and expectations (Owen et al., 2021a; von Schomberg, 2013). Similarly, integrating responsibility from the beginning phase of the venture creation process would enable the creation of socially responsible ventures that could benefit both firms as well as society (Lubberink et al., 2019; Zahra & Wright, 2016).

Although the framework for responsible innovation provides practical insight into integrating responsibility in the innovation process (e.g. Asante et al., 2014), information on the practical implications of RI in general and for business innovation in particular is scarce. The challenges and opportunities of adopting and implementing RI in innovation and entrepreneurial activities need to be critically analysed and empirically explored. Most of the research to date on RI has examined 'what' or 'why'; little research has been conducted on 'how' (Blok & Lemmens, 2015; Jakobsen et al., 2019; Long et al., 2020; Scholten & Blok, 2015; Tabarés et al., 2022; Thapa et al., 2019). Furthermore, most of the research on RI has stemmed from a policy or socio-ethical perspective, focusing mainly on academic R&D environments (Bernstein et al., 2022; Novitzky et al., 2020; Owen & Pansera, 2019), while most innovations are carried out in the business sector (Owen et al., 2021a; Scholten & Blok, 2015; Stahl et al., 2017). Therefore, policymakers and business sectors have a significant role in making RI of practical value. However, the study so far shows that RI in the industrial context is partially targeted and fails to have an impact on the industrial community (Auer & Jarmai, 2018; Lubberink et al., 2017; Novitzky et al., 2020; Owen et al., 2021a; Tabarés et al., 2022).

It is equally important that RI concepts, tools and methodologies should align with the current industrial policy practices (Dreyer et al., 2017). Furthermore, policymakers, funders, industry actors and entrepreneurs should see the perceived benefit of adopting and practising RI in innovation and entrepreneurship policies and practices (Lubberink et al., 2019; van de Poel et al., 2020). Despite growing bodies of RI literature on industry (e.g. Blok et al., 2015; Flipse & van de Loo, 2018; Garst et al., 2017; Gonzales-Gemio et al., 2020; Long & Blok, 2018; Lubberink et al., 2017, 2019), RI has not clearly articulated how the firms specifically start-ups integrate RI dimensions in innovation and entrepreneurship management. Therefore, there is a need to explore whether and how RI can be integrated into the innovation and entrepreneurship process of firms in the context of grand societal challenges.

Furthermore, grand societal challenges are complex problems (Rittel & Webber, 1973) where the needs and expectations of stakeholders, users and the public differ. They involve multiple interrelated causes and consequences, and the production of more disciplinary knowledge cannot reduce associated risk (Marschalek et al., 2022; Timmermans et al., 2020). Therefore, innovation approaches focused on problem-solving through problematisation (Volkema, 1983) and a classic linear techno-scientific approach may not be able to provide optimal solutions to the grand societal challenges (Marschalek et al., 2022). The RI approach in innovation and entrepreneurship could be viable (Bernstein et al., 2022; Blok, 2022; Marschalek et al., 2022; Timmermans et al., 2020).

Therefore, there is a need to investigate what values RI adds to innovation and entrepreneurship, specifically innovation and entrepreneurship management of start-ups.

3.3.3 Outcomes

The outcomes of innovation and entrepreneurship are not merely products and services, or the type of ventures created. They should be evaluated regarding socioeconomic, socio-ethical, and socioecological values created in society. The outcomes of innovation and entrepreneurship are unknown priory. Limiting the analysis and reflection of innovation and entrepreneurship outcomes is difficult without critically looking at their concrete manifestations (Callon & Lacoste, 2011). Their impact appears on notice only when they are commercialised, adopted, and bring into use. What if the negative consequences begin to appear? Should it be ignored and continued until unrecoverable damage has been done, or find an alternative to prevent complete disaster? These are the essential issues that firms and associates should consider to restore public confidence in science, innovation and entrepreneurial activities (Owen et al., 2021b; Owen et al., 2021a; von Schomberg, 2019). Therefore, firms', policymakers' and governments' role is critical during the execution of innovation and entrepreneurial outputs into desirable, sustainable and responsible outcomes (Vesnic-Alujevic et al., 2016; Garst et al., 2017; Stahl et al., 2017).

On the one hand, there is growing consensus among policymakers, scholars, governments, and the industrial community that addressing societal challenges without increased innovation and entrepreneurial impacts cannot be imagined (European Commission, 2011, 2014a; McCann & Ortega-Argilés, 2015; Bachtler et al., 2017). High-tech innovations such as nanotechnology, biotechnology, and digital technology are of higher priority to governments and the industrial community (Romig et al., 2007). On the other hand, there are growing concerns about increased negative externalities, such as climate change and growing disparity, increasing the credibility of innovation and entrepreneurship in contributing to widening grand societal challenges (Martin, 2016; Soete, 2019; Zahra & Wright, 2016).

Therefore, measuring innovation and entrepreneurial outcomes in terms of patents (e.g. Basberg, 1987; Griliches, 1998), innovation rates, or the number of venture successes might not reflect their contributions in creating socioeconomic, socio-ethical, and socioecological values for stakeholders and the public (Jirotka et al., 2017; Stahl et al., 2017).

Examining the number of innovative products or services produced, ventures created, patents registered, spin-offs produced, or the methods of production or productivity will not ensure positive changes in society. It requires structuring, reviewing, and evaluating the impact of innovation and entrepreneurship outputs (Owen et al., 2013b; Zahra & Wright, 2016). The rationale behind this is that innovation and entrepreneurship are expected to deploy for the socioeconomic and

socioecological value creation to address grand societal challenges and take care of the future (Bessant et al., 2005; Choi & Gray, 2008; Owen et al., 2013a; Rip, 2014; Zahra & Wright, 2016; Von Schomberg, 2019).

RI suggests that innovation and entrepreneurship policies and activities consider previously overlooked negative externalities, concerns and dilemmas induced by innovation and entrepreneurial outputs to increase the desirable, sustainable, and responsible outcomes. Furthermore, there are growing assumptions that RI dimensions could facilitate firms, entrepreneurs, managers and policymakers to evaluate the right impact of innovation and entrepreneurship outcomes (Stilgoe et al., 2013; Stahl et al., 2017). It can be instrumental in mitigating risks and uncertainty associated with the impact of innovation and entrepreneurial ventures (Bernstein et al., 2022; Blok, 2022; Owen et al., 2021a; von Schomberg, 2019). RI studies on the industry so far have looked at the responsible product and services as outcomes of the RI approach in innovation (e.g. Flipse & van de Loo, 2018; Long et al., 2020; Oftedal et al., 2019; Stahl et al., 2017).

Therefore, there is a need to investigate whether and how the RI approach to innovation and entrepreneur activities makes it possible to shape innovation and entrepreneurial outcomes in socioeconomic, socio-ethical and socioecological value creation (von Schomberg, 2013) with increased societal impact (Burdge & Vanclay, 1996; Daedlow et al., 2016; Herrera, 2016). This thesis defines social impact as the consequences of innovative solutions in society when brought into use

and their capability to address societal problems at the regional level and national or global levels (Burdge & Vanclay, 1996).

3.4 Summary

There is a growing belief that RI can be an alternative frame for regional policies and innovation and entrepreneurship policies and practices (Stilgoe et al., 2013; Schot & Steinmueller, 2018). It can play a central role in governing regional policies, innovation, and entrepreneurship practices towards increased societal impact. For such an initiation, the purpose (why), the process (how) and the outcomes (what) of innovation and entrepreneurship policies and practices should be aligned and reflected continually (Stilgoe et al., 2013; Jirotka et al., 2017; Stahl et al., 2017). However, its normative nature and ambiguity in operationalizability demand understanding and possible means of its implementation in innovation and entrepreneurship policies and practices (Timmermans & Stahl, 2014; Blok & Lemmens, 2015; Ribeiro et al., 2018). Furthermore, the purpose, the process and the outcomes of innovation and entrepreneurial activities need continual reflection to achieve the overall impact of innovation and entrepreneurship. In 2013, Stilgoe and colleagues proposed a framework for RI. The framework, although inherently context-dependent, bears broader applicability

(Stilgoe et al., 2013). Yet how the RI framework contributes to reflecting and governing the purpose, process, and outcomes of regional policies and innovation and entrepreneurship practices is not apparent.

Furthermore, regional policies shape innovation and entrepreneurial trajectories in the region since firms that are the primary driver of innovation are embedded into the regional ecosystem. Regional studies have viewed economic activities and innovation in the space context (e.g. Boschma & Martin, 2010; Solheim, 2017) targeted towards regional development. However, these studies consider the governance of innovation and entrepreneurship as given, overlooking the negative externalities due to innovation and entrepreneurial activities. Hence, the purpose of regional policies needs to be articulated and reflected to achieve overall regional goals. RI can facilitate the shaping of regional policies to achieve overall goals. However, the emphasis on RI has been more on governance but less on its specificities.

Furthermore, its implications for regional policies and innovation and entrepreneurship policies and practices are scant. Additionally, whether, why, how or to what extent RI can be conceptualised and operationalised within innovation and entrepreneurship policies and practices remains ambiguous (Owen et al., 2012). Also, it is still unclear whether, how or to what extent RI integration in innovation and entrepreneurial activities facilitates responsible and sustainable outcomes with increased societal impact. Overall, this thesis addresses three research agendas. The first research agenda explores the concept of RI, focusing on its purpose and

its implications for regional policies. Paper I appended in this thesis explores the understanding of RI, its purpose and implications for regional development. Furthermore, the paper outlines whether and how RI could contribute to sustainable and responsible regional policies, innovation and entrepreneurial policies and practices to achieve overall regional goals. Similarly, Papers II and III explore the need and approaches to articulating the purpose of innovation and entrepreneurship process to contribute to regional goals.

Accordingly, firms and entrepreneurs play a vital role in driving potential innovation that can contribute to addressing grand societal challenges and realising overall regional goals. Since they have a significant stake in the regional innovation and entrepreneurship ecosystem, their innovation and entrepreneurial activities matter (Adner, 2006). This also implies what, why, where, and how they innovate (Bessant, 2013). It also matters how they identify and exploit opportunities in entrepreneurial processes (Dees & Anderson, 2006; Yitshaki & Kropp, 2016). Identifying opportunities and innovating in the context of grand societal challenges is complex. Discourses on RI suggest that it can be a viable approach to innovation and entrepreneurship purpose, process and outcomes to benefit from innovation and entrepreneurship (Owen et al., 2021a; von Schomberg, 2019).

However, firms and entrepreneurs need to adopt and integrate RI into innovation and entrepreneurship. The second research agenda of this thesis explores the integration of RI in the innovation and venture

creation and firm development process. Paper II and Paper III address these issues. Specifically, Paper II explores the inclusion of stakeholders and users in the innovation process to find optimal desirable solutions through need-solution interactions. Paper III explores the role of RI in building opportunity confidence for socially responsible venture creation and firm development.

Finally, the outcomes of innovation and entrepreneurial activities need to critically reflect on whether their activities align with the purpose and process. How the RI approach facilitates this and how such initiatives of a firm facilitate sustainable, desirable, and responsible outcomes with increased social impact needs further exploration. The third research agenda explores the outcomes of RI initiatives in innovation and organisation development. Paper IV explores initiatives of business organisations in anchoring the RI approach that can assist in creating and spreading positive social impact.

To sum up, Paper I reflects on the purpose, Paper II and III on the process and Paper IV the outcomes of innovation and entrepreneurial activities. Together, they explore how to address the grand societal challenges and achieve regional goals.

4 Methodology

Different research methods and methodologies have been used in social research depending on the researcher's position on truth and reality (Cohen, Manion, & Morrison, 2002). This chapter therefore presents methodological approaches used to answer the research question of this thesis. First, the philosophy of science and the choice of the philosophical approach adopted in this research are presented. This is followed by a discussion on the choice of research design, data collection and analysis process.

4.1 Philosophy of science

Philosophy of science informs us of the nature of the phenomenon examined (ontology) and methods for understanding it (epistemology) (van de Ven, 2007). Whether explicitly or implicitly, social scientists rely on the philosophy of science to interpret the meanings, logical relations, and concerns of our observational and theoretical statements (van de Ven, 2007; Alvesson & Sköldberg, 2009). Different scientific paradigms are often used while discussing the philosophy of science in the field of organisational and management research.

This research was guided by a critical realist perspective. It imposes that reality is real but only imperfectly and probabilistically apprehensible and exists independent of our knowledge of it (Denzin & Lincoln, 2005; Alvesson & Sköldberg, 2009). The research was based on the following principles:

- There is a real world out there, but our individual understanding of it is limited (Lincoln et al., 2011).

- All facts, observations, and data are implicitly or explicitly theory-laden. As with any scientific knowledge, social sciences have no absolute, universal, error-free truths (van de Ven, 2007; Lincoln et al., 2011).

- There is no such inquiry which is value-free and impartial; rather, each is value-full. Some methods are better justified than others depending on the phenomenon (van de Ven, 2007)

- Knowing a complex reality is only possible through the use of multiple perspectives, and robust knowledge is a product of theoretical and methodological triangulation (van de Ven, 2007; Alvesson & Sköldberg, 2009; Lincoln et al., 2011; Maxwell, 2012).

The research aimed to understand and build knowledge on RI and its application to regional policies and innovation and entrepreneurship purpose, process, and outcomes through closely following RI discourses and interacting with firms and stakeholders in the regional innovation and entrepreneurship ecosystem.

Consistent with the critical realist epistemological position, understanding the phenomenon under study is possible through explanation and interpretation (Mingers, 2006) and different methodologies and analytical processes (Mingers, 2006; Maxwell,

2012). The process began with a review of the literature on RI and prior themes derived from literature and had a deductive character. Inductive reasoning was evident as interview and observational data were coded to extract and identify patterns and connected meaning as the analysis proceeded. The inductive reasoning supported the generation of new theories to explain the social process of RI integration in regional policies and innovation and entrepreneurial practices.

4.2 Research Design

The research design of a study is a scheme that determines how the study should be conducted to realize the purpose of the study to answer the research question (Blaikie, 2010; Maxwell, 2012; Patton, 2014). Thus, research design includes types of data to be collected, data collection tools and procedures, data analysis plan, and selection of sites for collecting data (Edmondson & McManus, 2007).

The thesis adopts a qualitative approach involving two different research designs, a systematic literature review (SLR) (Tranfield et al., 2003), and a case study (Eisenhardt, 1989; Yin, 2003).

The concept of RI is identified as nascent as it is still in a developing phase. For such a nascent state of theory and research, the data is collected through interviews, observations, documents, or other materials from field sites relevant to the phenomenon of interest (Edmondson & McManus, 2007). The concept of RI needs to be

explored further for theory building. Therefore, the research method needs to allow for the generation of rich data (Lee, 1999). The appropriateness of the choice of method for the present research is also supported by Edmondson & McManus (2007) in their methodological fit of a research framework. The framework classifies the state of prior theory and research as nascent, intermediate, and mature and recommends a suitable methodology for each category. Since RI is a relatively young field, characterised as nascent, an exploratory qualitative research approach was deemed a fruitful strategy (Edmondson & McManus, 2007). Furthermore, to overcome the ambiguity about RI, there is a need to keep up with state-of-the-art RI. Therefore, a systematic literature review methodology (Tranfield et al., 2003) was deemed advantageous (Snyder, 2019).

Synthesizing the previous works on qualitative methods (Miles & Huberman, 1994), the design of case study research (Yin, 1981, 1984), and grounded theory building (Glaser & Strauss, 1967), Eisenhardt (1989) proposed a road map for building theories from a case study research. According to Eisenhardt (1989), building theories from the case study research approach is especially appropriate in new topic areas, and the resultant theory is often novel, testable, and empirically valid. In addition, Eisenhardt (1989) explicitly examined the appropriateness, strengths, and weakness of theory building from the case study approach. Therefore, the case study approach is deemed the best-suited approach for the present study (Perry, 1998; Gerring, 2006; Emmel, 2013). The choice of a case study approach for this research will follow the

recommendation for the research strategy by Yin (2003) and Eisenhardt (1989). Therefore, the thesis adopts two research designs to answer the overarching research question.

4.2.1 Systematic literature review (SLR) approach

The Paper I appended to this thesis used a systematic literature review. A systematic literature review is a transparent and reproducible approach which enhances the quality of the review process and its findings (Tranfield et al., 2003). Since RI is an emerging concept, little is known about its purpose, process and outcomes, as well as its implications in regional studies. Therefore, the PhD thesis adopts the SLR approach to gain insight into the conceptual development of RI and its implications for regional studies and vice versa to draw knowledge that policymakers and practitioners associated with innovation and entrepreneurship policies and practices can apply.

Data were collected from 126 conceptual papers on RI/RRI and were analysed by thematic analysis (Braun & Clarke, 2006; Jones et al., 2011).

4.2.2 Case study approach

Papers II, III and IV used a case study approach. There are several reasons for adopting a case study approach for this thesis. First, a case study is a suitable research strategy that allows researchers to obtain a detailed understanding of social phenomena (Yin, 2014): integration of RI dimensions in innovation and entrepreneurial activities in the case of this thesis. Second, the limited research on responsible innovation and

its impact on innovation and entrepreneurial activities and limited theories on responsible development and deployment of digitalisation of healthcare and welfare services warrant a theory- building rather than theory testing (Eisenhardt, 1989; Eisenhardt & Graebner, 2007). Third, through the case study approach, it is possible to explore contemporary phenomena within their real-life context (Patton, 2014; Yin, 2014), enabling access to essential data and findings of the complex dynamics of responsibility integration in innovation and entrepreneurial activities. Fourth, the overarching research question of this thesis and the research questions of the individual research papers of this thesis begin with 'how' and seek to explain certain circumstances. In such a context, a case study is the most appropriate research strategy (Yin, 2014).

A case study focuses on a detailed understanding of particular settings (Eisenhardt, 1989) and can involve either single or multiple cases and numerous levels of analysis (Yin, 2003; Gustafsson, 2017). The first two papers used multiple case studies, and the last paper used a single case study. Each case study's methods serve a specific purpose. A single case study increases the understanding of complex social phenomena and enhances new knowledge development (Gerring, 2006; Creswell & Poth, 2016). It allows a deeper understanding of exploring the subject (Gustafsson, 2017). In addition, a single case allows us to describe existing phenomena richly, question existing theoretical relationships, and explore new ones (Gustafsson, 2017). Accordingly, a single case study design (Paper IV) allowed us to make a careful study of the RI

initiatives in innovation and business development and resulting outcomes (Yin, 2003; Creswell & Poth, 2016; Gustafsson, 2017).

Multiple case studies create a more robust theory grounded in varied empirical evidence (Eisenhardt & Graebner, 2007). More specifically, they allow us to understand similarities and differences between the cases and enable us to analyse data within and across cases (Gustafsson, 2017). Therefore, they allow a broader exploration of research questions and theoretical development (Eisenhardt & Graebner, 2007). Thus, a multiple case study design (Papers II and III) aims at adding knowledge on the operationalisation of RI in innovation and entrepreneurship policies and practices.

A case study design allows researchers to conduct an in-depth investigation and data triangulation from multiple sources, including secondary data sources. The methodology used in each paper in this thesis is presented in the table below.

Table 2: Methodology used in the papers

Paper title	Unit of analysis	Type of study	Case selection
1. Responsible Research and Innovation: A Systematic Review of the Literature and its Applications to Regional Studies	Concept of RI	Systematic literature review	126 conceptual papers on RI
2. Governing digital innovations for responsible outcomes – the case of digital healthcare and welfare services	Firm digital innovation	Multiple case study	Six start-up firms
3. Digitalisation and Responsibility in New Venture creation and Business development: The case of digital healthcare technology	Firm new venture creation	Multiple case study	Nine firms at different life stages
4. Responsible Research and Innovation: Innovation initiatives for Positive Social Impact	Firm Innovation and business development	A single case study	A single firm

4.2.3 Empirical Setting

The empirical setting for Papers II, III, and IV consisted of nine firms at different life stages (start-ups, launched, and established) associated with digital innovation and entrepreneurship in healthcare and welfare services. All these firms are members of Norwegian Smart Care Clusters (NSCC).

The aim of this study was to understand the integration of responsible innovation in innovation and entrepreneurial processes in the context of digital healthcare and welfare services. Since all the firms in NSCC are engaged in digital innovation in the healthcare and welfare sector, and most are start-ups, closely following their innovation and entrepreneurial activities would allow access to rich data. This would facilitate uncovering nature as it occurs and provide a meaningful conceptual description that would enable further scientific inquiry into the phenomenon.

Furthermore, the NSCC was established as a regional innovation policy initiative to promote digital innovation and entrepreneurship within healthcare and welfare services in the region. In addition to innovative firms, its members include municipalities, hospitals and government institutions associated with healthcare and welfare services. The cluster organises workshops and events to bring together firms and stakeholders to promote digital healthcare and welfare services in the region and beyond. Following the NSCC, its members, both firms and stakeholders and workshops and events would be a source of rich data for the study.

4.2.4 Case selection

In answering the overarching research question of this thesis, each case was studied from different perspectives (societal actors, stakeholders, and firms). Therefore, for this study, the case included a firm, its current and potential users, and stakeholders, including a local municipality,

policymakers, public funding bodies, healthcare experts, educators, and facilitators associated with healthcare and welfare services.

The case selection followed a homogeneous sampling strategy (Patton, 1990). Thus, the following criteria were adopted while selecting the cases: (1) Start-up firms or innovation projects within existing small or medium-sized firms focusing on the digitalisation of healthcare and welfare services. This approach was adopted to allow for some variations in innovation and entrepreneurship processes and comparisons among start-ups. (2) Start-ups or innovation projects in established firms in an early stage of development, to ensure homogeneity. Hence, factors associated with the integration of responsibility in innovation and entrepreneurial activities could be identified (Lipset, 1990).

4.2.5 Unit of analysis

The unit of analysis is based on the study's analytical approach (Patton, 2014) and is determined by the study's research question (Blaikie, 2010; Yin, 2014). This thesis's overarching research question explores responsible innovation and its implications for regional policies and innovation and entrepreneurial practices in the context of digital healthcare and welfare services. Therefore, the unit of analysis are the concept of RI -Paper I and firms-Papers II, III, and IV.

In this PhD thesis, firms are defined not as standalone units with a bounded context but as expansive ones with fluid and porous boundaries influenced by the environment and vice versa (Solheim, 2017). Thus,

while the firms are influenced by the entrepreneurs and employees within, it is also part of the innovation system, whether regional (Asheim et al., 2011; Asheim et al., 2016), sectoral or technological (Edquist, 1997, 2006), and national (Lundvall, 2010). Therefore, the thesis takes a micro-level view by looking specifically at the firm level and recognising that these firms exist within a broader innovation system, taking a macro view by drawing implications for regions. Thus, Paper I takes RI as the analysis unit, places it within a regional context, and makes recommendations on the role of policymakers can play to help firms to implement RI practices as well as leverage on the same. Papers II, III and IV look specifically at firms but take an innovation systems perspective taking innovation to be an interactive process within the firm, among firms and in the regional innovation system with other innovation actors such as government, citizens, and civil society. These levels of analysis enabled a more holistic understanding of the totality of which the firms are a part of the region (Maxwell, 2012).

4.3 Data collection

The basis of this thesis is a systematic review of the RI literature and the longitudinal data collection associated with innovation and entrepreneurial activities in the digitalisation of healthcare and welfare services. For the systematic literature review (Tranfield et al., 2003), the thesis includes 126 conceptual papers on RI. For the empirical study, data collection includes sources of primary and secondary data, implying a triangulation strategy (Yin, 2014). Primary data includes semi-

structured interviews and observations. Secondary data includes information available on firms' home pages, documents that were provided by the firms, and a press release about the products or services of the firms. Data collection also includes policy documents associated with healthcare and welfare service provisions, and eHealth policy. Information obtained while attending conferences and workshops associated with healthcare and welfare service promotion also comprises additional data for the study. The purpose of adopting a triangulation strategy in our research is to produce a more balanced picture of the phenomenon and to serve as a cross-validation method (Elliott & Timulak, 2005).

4.3.1 Interview process

In-depth interviews were conducted with informants to understand their subjective thoughts and experiences (Britten, 1995). The interviews were conversational rather than structured interviews, most suited to the case study approach (Yin, 2014). In total, 36 semi-structured face-to-face interviews were conducted during 2017-2019[1]. The interviews were conducted with representatives from firms (CEOs and project managers), stakeholders, experts, educators, and user representatives over two periods to provide a balance of opinions from different perspectives and levels of responsibility (Eisenhardt & Graebner, 2007). The interview questions were developed to explore the purpose and process of

[1] Data were obtained from secondary sources following information available on the firms' and NSCC's web pages to follow up on the firm development.

digitalisation of healthcare and welfare services and were also based on the principal dimensions of RI (Stilgoe et al., 2013), the RRI maturity model (Stahl et al., 2017), and official reports on healthcare and welfare services (Official Norwegian Reports, 2009, 2011) gathered before interviews were commenced (Yin, 2014). Considering the informants' different perspectives, we designed and relied upon different interview guides (Appendices A1, A2 &A3) for firm representatives, stakeholders, users, and other actors associated with healthcare promotion to find out their shared interest. For instance, for firm representatives, the interview questions were focused on finding out the purpose, process and product or services, and questions were more open-ended ('what,' 'how', and 'why') questions to allow the informants freedom so that they would provide information that they might otherwise, would not have provided by posing static questions (Elliott & Timulak, 2005). For stakeholders and other relevant actors associated with healthcare and welfare service innovation, questions were prepared to obtain their views on the type of research and innovation they think would be needed in the days to come, their roles and responsibility in promoting responsible research and innovation in the region, and what kinds of research and innovation are prioritized and supported. Who decides what types of research and innovation are essential to regional development? How important do they feel responsible development and deployment of products/services are for regional transformation, and what efforts have they made to contribute to this? Each interview lasted 60–80 minutes during the first round and 40–60 minutes in the second round. All the interviews were

recorded and transcribed verbatim (Alvesson & Sköldberg, 2009; Yin, 2014), generating 675 pages and 270,648 words of data.

4.3.2 Written documents

Secondary data are additional information relevant to case study research (Yin, 2014). Various reports, newsletters, websites, and policy documents were the secondary sources for secondary data for this study. These documents primarily helped to improve understanding of the purpose and motivation of activities and events that had taken place in association with healthcare and welfare service promotion before interviews were conducted (Alvesson & Sköldberg, 2009; Maxwell, 2012).

4.3.3 Workshops, conferences and observations

Additional data in association with the promotion of digitalisation of healthcare and welfare services for the study was obtained while participating in seminars and workshops. We had the opportunity to observe product development (in one of the projects of our case firm) and telemedicine procedures. We interacted with the participants in the seminars and workshops. We gathered data from two workshops hosted by NSCC, an eHealth conference, two smart city conferences, and one healthcare conference held in Stavanger, Norway, by extensively taking memos. These notes were mainly descriptive and observational but also included our interpretations and reactions, which we clearly labelled as such (Elliott & Timulak, 2005).

4.4 Data analysis

The data analysis involved a systematic organisation and synthesis of collected data and required a highly iterative process comparing the emerging findings with extant theory (Miles & Huberman, 1994; Eisenhardt, 1989). We bear in mind that qualitative data analysis is not an easy or straightforward task; it requires substantial time and effort and involves challenges in reporting the richness and value of the data (Polit & Beck, 2008).

The thesis adopted thematic analysis (Braun & Clarke, 2006) and used interview transcripts and written field notes as the primary data sources. However, for the systematic review of the literature (Paper I), conceptual papers on RI were the data source for the analysis. The data analysis began during data collection and used coding procedures to discern patterns in qualitative data to establish the meaning of the informants through descriptive codes, categories and interpretive schemes (Gioia & Pitre, 1990; Strauss & Corbin, 1997; Ryan & Bernard, 2003; Elliott & Timulak, 2005).

One hundred twenty-six conceptual papers on RI were subjected to the final analysis in the Paper I appended to this thesis. The analysis followed the reading guide developed by the authors, which included a review of key themes, theories, and contributions toward theory and practice. After the initial review, the major themes of the papers were deduced from the key concepts, ideas and discussions and conceptual linkage of expression presented in the papers (Ryan & Bernard, 2003;

Thorpe et al., 2005) and categorised into RI drivers, RI tools, RI outcomes and RI barriers.

In the other papers in this thesis, the interview data recorded during interviews were transcribed verbatim (Alvesson & Sköldberg, 2009; Yin, 2014). Other data in the form of notes are prepared. The whole data set was read and re-read several times, drawing a complete picture of the studied phenomenon (Miles & Huberman, 1994). The contents of the data set were coded through a manual coding approach (Saldana, 2015). The content of the codes was then grouped under the predefined themes, inclusion, anticipation, reflexivity, and responsiveness. Simultaneously data editing was done to omit redundancies, repetitions, and unnecessary digressions. However, special attention was made not to overlook the essential and relevant aspects of the phenomenon. The papers included instances of data except to increase the results' transparency and trustworthiness. Furthermore, reflexivity and respondent validation were considered in the construction and analysis of data to address issues of validity and reliability concerning the results(Maxwell, 2012; Elo et al., 2014), which are elaborated on in the subsequent sections.

4.4.1 Research quality measures

Although research quality criteria are often not quoted explicitly in research papers, they are implicit in how researchers operate (Hlady-Rispal & Jouison-Laffitte, 2014). Since it is the case of the included papers of this thesis, it is essential to reflect on the study's quality measures (Maxwell, 2012). The research quality criteria of

confirmability, dependability, credibility, and transferability within qualitative inquiry are adopted as quality measures. However, these criteria, despite corresponding to quality criteria for quantitative inquiry, are not equivalent to the quantitative method (Miles et al., 2014).

4.4.2 Confirmability (corresponds to objectivity)

Confirmability is associated with researchers' ability to keep potential biases under control and explicit about the biases that exist. Consequently, I have reflected on how the data were collected, analysed, and used for drawing conclusions in the research papers included in the thesis (Miles et al., 2014). Furthermore, I have reported empirical quotations to exemplify and illustrate the informants' views in the text wherever applicable (Maxwell, 2012). Furthermore, I have included information about the development of this thesis and the methods used in section 4.3.2 (Miles et al., 2014).

4.4.3 Dependability (corresponds to reliability)

Dependability is associated with whether the study is consistent across research and methods. The interview guide was prepared before the interviews. The follow-up interviews were conducted to explore further changes and development in the innovation and entrepreneurial process. The co-authors were also involved in the data analysis as well as research findings (Miles et al., 2014).

4.4.4 Credibility (corresponds to internal validity)

Credibility relates to the trustworthiness of research findings and the degree the results make sense, and how convincing they are to the audiences (Maxwell, 2012; Miles et al., 2014). Accordingly, the initial findings were discussed with the interview informants prior to the second round of interviews (Patton, 2014). Furthermore, the study is strengthened through different triangulation strategies (Healy & Perry, 2000; Patton, 2014). Among the four types of triangulation (Denzin, 1978), data triangulation – the adoption of a variety of data sources in a study, and theory triangulation-the use of multiple perspectives to interpret a data set (Miles et al., 2014) are extensively applied mainly on Papers II, III and IV included in this thesis. Furthermore, this thesis adopts different theoretical frameworks to enable theory development on the complex processes of integrating responsibility in digital innovations and entrepreneurial activities (Eisenhardt, 1989; Eisenhardt & Graebner, 2007).

4.4.5 Transferability (corresponds to external validity)

Transferability refers to the degree to which the research findings are relevant and applicable to other contexts (Maxwell, 2012; Miles et al., 2014). Qualitative research often seeks to understand complex phenomena rather than statistical generalisation (Maxwell, 2012). Hence, the generalisability of qualitative research findings is a contested topic. Bearing this in mind, I sought to connect the study results with prior theory, thus enhancing transferability (Eisenhardt, 1989; Maxwell,

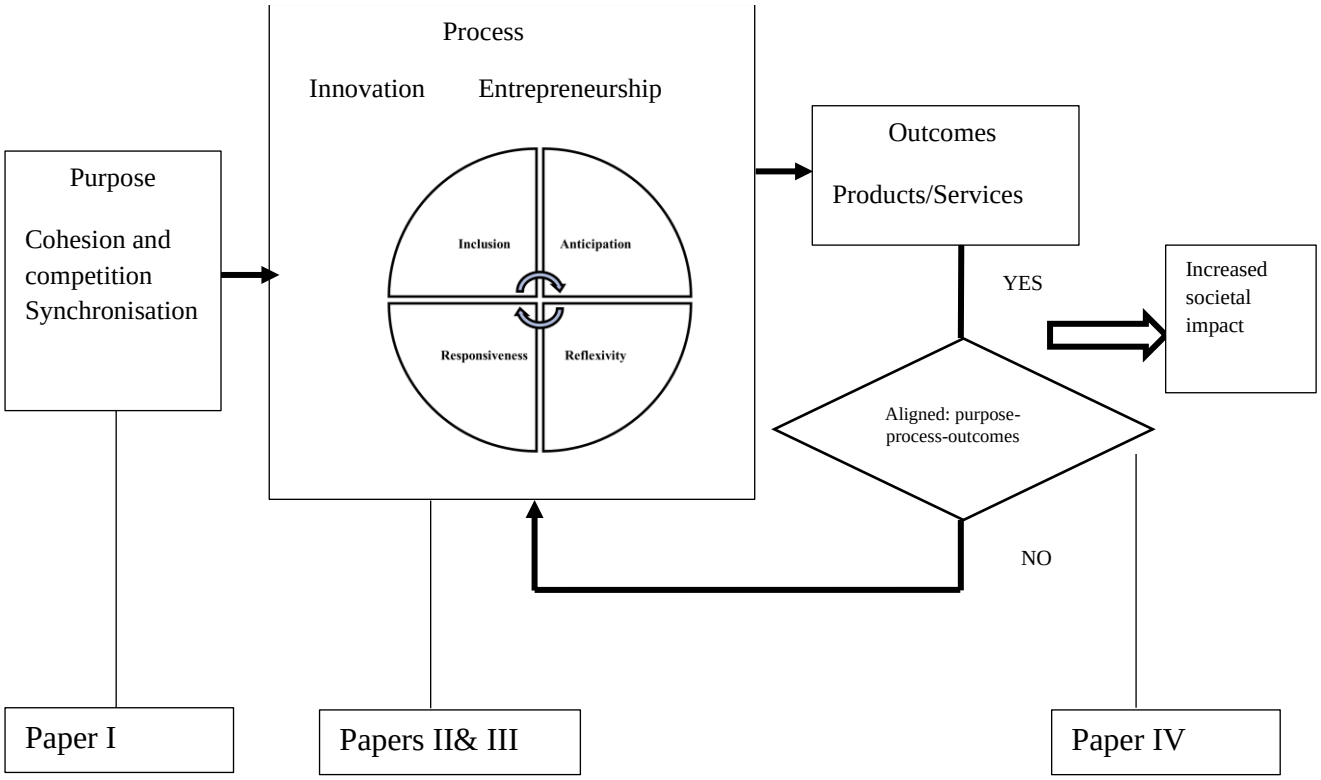
2012; Miles et al., 2014). The findings are also congruent with prior findings. However, the findings are extended in various aspects (Miles et al., 2014).

5 Summary of Research Papers

This chapter presents summaries of the four papers included in this thesis. While the first paper is a systematic literature review, the rest are empirical. Each paper addresses the specific research question. However, they are interconnected and contribute to addressing the overarching research question of the thesis. Furthermore, they together contribute to the understanding of the alignment of purpose, process and outcomes of regional policies, innovation and entrepreneurship policies and practices to achieve desirable, sustainable, and responsible outcomes for increased impact. Paper I explores the concept of RI, its purpose and its implication for regional policies in the context of sustainable regional development. Paper II explores the integration of RI in the innovation process and its implications on the governance of the innovation process at firms for desirable, sustainable, and responsible products and services. Paper III explores the integration of RI into entrepreneurship and its implication for building opportunity confidence for venture creation and firm development. Finally, Paper IV explores RI initiatives and outcomes of innovation and entrepreneurial activities.

Figure 2 illustrates the logical and conceptual relation between the different theoretical frameworks. Furthermore, the figure indicates which paper addresses the different theoretical frameworks and topics. Finally, Table 3 presents a brief overview of the included papers.

Figure 2: Conceptual relation between theoretical frameworks



5.1 Paper I: Responsible Research and Innovation: A Systematic Review of the Literature and its Applications to Regional Studies

Drawing on RI and regional studies literature, the paper brings to the fore the significance of RI in shaping the purpose of regional policies and practices, including innovation and entrepreneurship policies and practices, in achieving the overall regional goals. Different policy instruments have been deployed at the regional level to achieve sustainable development (e.g. Foray, 2014; Bachtler et al., 2017). Despite having made a significant transformation in regional economic development and human well-being, regional policies and practices, including innovation and entrepreneurship, have raised several critical concerns and dilemmas (Soete, 2010; Owen et al., 2013b; Soete, 2013; Martin, 2016; Zahra & Wright, 2016). The growing disparities due to unequal distribution of gains from innovation (Rodríguez-Pose, 2018; Storper, 2018; Iammarino et al., 2019) within and between regions and other widening grand societal challenges put a question about the credibility (Owen et al., 2021 b; Schot & Steinmueller, 2018a) of such policies initiatives for the sustainability of regions (Fagerberg et al., 2013; Owen et al., 2013b). Therefore, there is a need for an inclusive and sustainable governance mechanism (Irwin, 2006; Hajer, 2009; Guston, 2014; Hester et al., 2015) as an alternative approach to the current research and innovation governance mechanism. RI has emerged as a transformative policy framing with an ambition to govern innovation and

entrepreneurial activities (Coenen, 2016; Schot & Steinmueller, 2018; Owen & Pansera, 2019).

RI aims to restore public confidence in science and innovation (Owen, 2009; Owen et al., 2012) to achieve an inclusive and sustainable future (Owen et al., 2013a) through responsible governance of science and innovation for desirable outcomes with increased impact (von Schomberg, 2011; Owenet al., 2013b; Stilgoe & Guston, 2017). The emphasis is on the inclusion of a diversity of stakeholders and the public at the very beginning of the research and innovation decisions to collectively configure the purpose of research and innovation policies and practices (von Schomberg, 2013) and to direct them to generate the right impact (Illies & Meijers, 2009; Sutcliffe, 2011; Rip, 2014).

Referring to the ongoing debates on regional studies and RI, it could be a viable approach for sustainable regional development, taking into consideration its implications for regional policies and practices and innovation and entrepreneurship policies and practices. However, the critique that it is normative (Ribeiro et al., 2018) and highly ambiguous in terms of its operationalizability in policies and practices (Blok & Lemmens, 2015; Forsberg et al., 2015) necessitated exploring RI, its purpose and whether or not it can be brought into practice. Thus, this paper contributes to an increased understanding of RI, its purpose and potential applications to sustainable and responsible regional development. Furthermore, the paper contributes to how RI and regional studies can benefit from each other.

The findings indicate that RI has significantly gained attention from different disciplines over the last decades. Debate on RI is getting the centre of attention among academia and policymaking bodies. However, RI discussion and debate have to spread among business communities since most innovations happen in the private sector. Therefore, RI can play a vital role in sustainable regional development, depending on how well it will be integrated into regional policies, innovation and entrepreneurship activities. Furthermore, findings supplement current understanding by providing operational insights into how RI can be integrated into regional policies and innovation and entrepreneurship practices, focusing on RI drivers, tools, barriers, and outcomes.

From the ongoing debates on RI and regional studies and the findings of Paper I, it can be concluded that there is a potential opportunity for RI and regional innovation studies to contribute to the combined advancement of theory and practice collectively. Furthermore, for sustainable and responsible regional development, their synchronisation is vital to fulfilling the purpose of addressing grand societal challenges focusing on innovation and entrepreneurship based on the needs, values and expectations of the stakeholders in the regional ecosystem.

Firms and entrepreneurs as drivers of innovation and entrepreneurial initiatives in the regions, their adoption and implementation of the RI approach in innovation and entrepreneurship activities equally matter to achieve the overall regional goal of addressing grand challenges. Therefore, regional policies should incentivise firms to practice RI and

encourage firms to interact with users and stakeholders, co-create, ensure offerings' efficacy and safety, and maintain trust.

To summarise, RI initiatives in innovation and entrepreneurship policies and practices can facilitate sustainable regional development if the purpose is reflected via innovation and entrepreneurship processes and outcomes. This warrants firm-level innovation and entrepreneurship governance towards increased societal impact. However, firms need to integrate RI into their innovation and entrepreneurship process. For this to happen, firms and entrepreneurs must find it easy to integrate into their existing practices (Dreyer et al., 2017) and see the value of integrating and practising RI in innovation and entrepreneurship activities (van de Poel et al., 2020). Therefore, empirical studies are warranted to demonstrate the integration of RI and its implication in innovation and entrepreneurship processes and outcomes of such initiatives.

5.2 Paper II: Governing digital innovations for responsible outcomes– the case of digital healthcare and welfare services

Paper II draws on RI, innovation and problem-solving literature and explores the integration of RI dimensions in the innovation process and how they can govern the innovation process towards need-based solutions that are optimally desirable, responsible, and sustainable. Innovation is imperative in addressing the socioeconomic and socioecological challenges of society. However, harnessing innovations' full potential to benefit society depends on how firms develop innovations and how these

innovations are deployed to address societal challenges. This paper empirically explores the viable approach to integrating RI dimensions in the innovation process and managing digital innovation for sustainable innovation outcomes in healthcare and welfare provision.

Problem-solving literature emphasises how problems are being formulated and subjected to solving (e.g. Lyles & Mitroff II, 1980; Ben-Menahem, von Krogh, Erden, & Schneider, 2016). Although this approach has prevailed to be an efficient approach for developing innovative solutions, firms adopting it for innovativeness cannot rigorously envision the problem definition of the problem that they are attempting to address and articulate why those problems are essential (Spradlin, 2012).

In addition, the classical problem-solving approach often leads to solutions being pushed to the market rather than exploring the broader solution landscape with stakeholders and users' need-solution interaction (von Hippel & von Krogh, 2015). To find out a sustainable solution for the problem, identification of the root cause of the problem is necessary (Thomke, 1998; Thomke & Fujimoto, 2000). The integration of RI dimensions of inclusion, anticipation, reflexivity and responsiveness in the innovation process can be instrumental in governing and managing the innovation process for desirable innovation outcomes that are sustainable and responsible. Although all the dimensions are vitally important for the governance of the innovation process, the paper explicitly explores the inclusion dimension. Including a diversity of stakeholders and users early

in the innovation prosses, firms and entrepreneurs can access the potential solution through need-solution interactions.

The findings suggest that including a diversity of stakeholders and users enabled firms and entrepreneurs to need solution interaction that facilitated acquainting themselves with the actual problems that stakeholders and potential users were facing. Furthermore, they could analyse the problem's root cause and develop potential solutions. Firms and the engaged stakeholders gained the opportunity to collaborate, co-create and constantly refine the solutions to result in optimal desirable solutions that are sustainable and responsible. Additionally, the findings suggest that firms will likely identify needs, concerns, and expectations early on if stakeholders, especially the end users, are included earlier in the innovation process. Thus, firms can save resources and increase the probability of adoption and diffusion of their products and services, thus reducing their as well as stakeholders' and users' risk.

Despite the potential benefits of inclusion in the innovation process, firms, especially start-ups, find inclusion challenging due to resource constraints, power and information asymmetry and additional administrative burden. They find challenges in including vulnerable user groups in the innovation process. Furthermore, it was hard for them to ensure mutual commitment from the stakeholders and users to be engaged throughout the innovation process.

Furthermore, the paper extends the knowledge of how firms can manage innovation in the context of complex problems. It provides practical

insight into how RI can be integrated into the innovation management process and govern it for inclusive, sustainable, and responsible innovation outcomes.

5.3 Paper III: Responsible innovation approach in Venture creation and firm development: The case of digital innovation in healthcare and welfare services

Drawing on entrepreneurship and RI literature, this paper explores how firms and entrepreneurs build opportunity confidence in venture creation and firm development. Entrepreneurship literature has long advocated opportunity as the core of entrepreneurship (e.g. Stevenson et al., 1994; Shane & Venkataraman, 2000; Shane, 2004; Grégoire & Shepherd, 2012). Entrepreneurship scholars have advocated how entrepreneurs and firms acquire opportunities (e.g. Barney, 1991; Venkataraman, 1997; Sarasvathy, 2001). However, there is an ongoing debate that 'opportunity' itself cannot explain entrepreneurship (Alvarez & Barney, 2007; Klein, 2008; Davidsson, 2015). Furthermore, it could even be elusive in the context of complex problems (Eckhardt & Shane, 2003; Hsieh et al., 2007; Dimov, 2010; Davidsson, 2015).

Arguably, opportunity confidence (OC) (Dimov, 2010; Davidsson, 2015) is introduced as a crucial construct in venture creation and firm development (Davidsson, 2015). OC is a firm's or entrepreneur's evaluation of the opportunity and depends on various factors and degrees of favourability (Gemmell et al., 2012). For instance, OC depends on opportunity feasibility, self-efficacy (Dimov, 2010), customer and user

satisfaction (Bowen & Chen, 2001), and trust. In the context of grand challenges, building OC to create successful ventures and firm development is critical (Zahra & Wright, 2016) and, therefore, needs further exploration.

The paper explores how RI can be integrated into the venture creation process and how it facilitates firms building OC vital for new venture creation and firm development in the context of complex societal challenges such as healthcare and welfare services.

The paper contributes knowledge to building opportunity confidence in managing entrepreneurial activities. Furthermore, it contributes to the RI literature in an industrial context by studying factors that influence innovation, entrepreneurial decision-making, and strategic choice for responsible venture creation.

The findings suggest that although firms and entrepreneurs do not practice de facto RI, certain approaches in venture creation and firm development demonstrate a significant shift towards responsible practices. Despite motivation towards responsible innovation practices, the barriers to RI, such as resource constraints, institutional barriers, fear of information asymmetry, and lack of trust by professionals and users, restrict them. Nevertheless, firms that can include diverse stakeholders and users early in the venture creation process benefit by developing OC through knowledge acquisition and better anticipation of risk and alternatives. Furthermore, they could build trust by being reflexive and responsive to the stakeholders' and users' concerns, increasing their

confidence in decision-making. However, national innovation and entrepreneurship policy need to support and motivate entrepreneurial firms to integrate and practice RI approaches in their corporate activities.

5.4 Paper IV: Responsible Research and Innovation: Innovation initiatives for Positive Social Impact[2]

This paper draws on innovation, entrepreneurship, and RI literature and explores the outcomes of RI initiatives in the innovation and business development activities of an organisation.

Literature in innovation management and venture creation acknowledged innovation and entrepreneurship as a mechanism for competitiveness and firm growth (Gartner, 1989; Teece et al., 1997). In the run to gain competitiveness and superior profit, the focus has been chiefly on the output of innovation and entrepreneurial activities, mainly overlooking the outcomes of their impact on society (Martin, 2016). With the widening of grand societal challenges due to economic activities, including innovation and entrepreneurship, public pressure being mounted on policymakers, public and private sectors demanding to reflect on firms and entrepreneurs' social responsibility (Dees & Anderson, 2006; Lazonick, 2014; Zahra & Wright, 2016). Therefore, firms must address public concerns and focus on innovations based on societal values, needs and

[2] This paper was written as a contribution to the book 'Responsible innovation in digital health: Empowering the patient' (Iakovleva et al., 2019a). The book has an introductory theoretical chapter in which the central concept of RI is debated. Though the chapter was an empirical contribution, it is limited in theoretical discussion while focused on a case description and discussion, as requested by the book editors.

expectations (von Schomberg, 2013). Responding to public concerns about innovation and entrepreneurial activities benefits firms and society (Choi & Gray, 2008; Nicholls, 2009). Many are sceptical about whether the balance between competitiveness and social responsibility can be achieved (Dees & Anderson, 2006; Sutcliffe, 2011).

Arguably, the concept of RI's adoption and implementation in innovation and entrepreneurial activities can facilitate firms balancing between economic benefits and societal benefits (Rip & van Lente, 2013; Rip, 2014). It is assumed that such initiatives transform society and form a foundation for sustainable growth for businesses (Nicholls, 2009; Scholten & Van Der Duin, 2015; Zahra & Wright, 2016). The RI approach in innovation and entrepreneurial activities will facilitate anticipation of the unintended impact of innovation, thus increasing the chances of societal problems alleviation and positive social impact (Burdge & Vanclay, 1996). How RI initiatives in innovation and entrepreneurship can result in outcomes that address the grand societal challenge is still an unexplored topic. Therefore, this paper attempts to do so. In so doing, the paper contributes by identifying specific activities that can assist in building competitiveness for increased organisational sustainability and positive societal impact.

Findings suggest that adopting RI dimensions in innovation management and firm development facilitates alignment of the purpose, process, and outcome of innovation and entrepreneurial activities, ultimately resulting in broader societal impacts. Such organisational initiatives would lead to

sustainable organisational growth. However, organisational commitment and determination to adopt and implement RI in innovation and entrepreneurship by firms are crucial.

Table 3: Summary of the research papers

Title	Authors	Research Question	Objectives	Theory	Approach	Key findings
1. Responsible Research and Innovation: A Systematic Review of the Literature and its Applications to Regional Studies	Thapa Raj Kumar, Iakovleva, Tatiana & Foss Lene	How is RRI conceptualised in literature? And, to what extent can it be applied to the context of regional development and vice versa?	To understand the concept of RI and its operationalizability in regional policies, including that of innovation and entrepreneurship policies and practices. To explore its implications in regional innovation studies	RI, Regional innovation	Systematic literature review	RI and regional studies are compatible in many respects. Synchronisation of RI and regional studies offers potential for increased regional impact. Purpose, process and outcomes of research and innovation should be aligned for increased impact. Integration of RI can be enhanced with a focus on RI drivers, tools, barriers, and outcomes. RI dimensions can be integrated into regional policies and practices, including those concerning innovation and entrepreneurship. RI dimensions must be incorporated into practices for overall regional development sustainably and responsibly.

2. Governing digital innovations for responsible outcomes– the case of digital healthcare and welfare services.	Thapa Raj Kumar & Iakovleva, Tatiana	How does the inclusion of a diversity of stakeholders affect the governance of the innovation process in firms?	To explore how firms can integrate RI in the innovation process and manage and govern innovation for desirable, sustainable, and responsible products and services.	RI, problem-solving, need-solution interaction, innovation management and innovation governance	Multiple case studies	Firms can integrate and practice RI in the innovation process. For instance, they can include diverse stakeholders and users from the design phase of the innovation process. Firms include stakeholders and users at different stages of the innovation process and adopt different engagement approaches, non-participatory, symbolic and engaged participation. While all types of engagement approaches have advantages and disadvantages, engaged participation is the most appropriate in innovating solutions for the problems in the context of grand societal challenges. Including diverse stakeholders, especially end users, in the design phase of the innovation process allows firms to acquaint themselves with stakeholders' needs, values, expectations, and concerns about innovative products and services for problem-solving.

						Inclusion allows early need–solution interaction, reducing the pivotal moments benefiting stakeholders and firms. Despite the potential benefits of inclusion, firms and entrepreneurs, especially start-ups, face challenges in practising inclusion due to resource constrain, power and information asymmetry, lack of access to a broader stakeholder network, and the challenges of assuring mutual commitment for engagement.
3. Responsible innovation approach in Venture creation and firm development: The case of digital innovation in healthcare and welfare services	Thapa Raj Kumar & Iakovleva, Tatiana	To what extent does the RI approach contribute to building OC in venture creation and firm development?	To explore how firms and entrepreneurs can develop opportunity confidence in successfully creating new ventures and business development.	RI, entrepreneurship, venture creation, opportunity confidence	Multiple case study	Integration of RI dimensions in the venture creation process facilitates firms' building opportunity confidence for venture creation and firm development. RI dimensions of inclusion and anticipation facilitate product/service efficacy and feasibility confidence. Responsiveness and reflexivity promote access to essential resources for business development and build trust among stakeholders, which is critical to success. Furthermore, RI dimensions facilitate the OC of both firms and stakeholders; firms select the right

						venture idea, and venture and stakeholders adopt the right solutions. However, firms and entrepreneurs need support mechanisms to overcome the challenges of integrating RI in venture creation and firm development activities.
4. Responsible Research and Innovation: Innovation initiatives for positive social impact	Thapa Raj Kumar & Iakovleva, Tatiana	How do business organizations pursue responsible innovation in business development and create positive social impact?	To explore how firms can increase positive social impact through RI initiatives in innovation and business development.	RI, innovation, entrepreneurship	Explorative case study	Integration and practice of RI in the innovation and entrepreneurship process depend on organisational initiatives, motivation, and commitment. Organisational initiatives to practice RI in innovation and entrepreneurship processes facilitate social and organisational value creation. RI practices enhance organisational sustainability and increase social impact.

6 Conclusions and Implications

This chapter summarises the main findings and contributions of this thesis on how the RI approach facilitates regional policies and innovation and entrepreneurship practices in firms towards increased societal impact in healthcare and welfare services. The chapter first presents contributions from the thesis, followed by implications for practitioners and policymakers, limitations, and future research avenues.

6.1 Contributions of the thesis

Responsible innovation can be a transformative frame in response to regional policies, innovation, and entrepreneurship practices in the context of grand societal challenges (Owen et al., 2021 b; Ranga & Kim, 2023; Schot & Steinmueller, 2018; Stilgoe et al., 2013; von Schomberg, 2019). It can be a viable approach to addressing societal challenges, but it needs to be integrated into regional policies, innovation and entrepreneurship practices (Novitzky et al., 2020; Owen et al., 2013b). However, critics meant that RI is ambiguous and normative and, thus, may encounter operationalisation challenges (Blok & Lemmens, 2015; Pellé, 2016; Ribeiro et al., 2018; Timmermans & Stahl, 2014). Thus, while there is growing consensus that integration of RI dimensions in regional policies, innovation, and entrepreneurship processes is essential for addressing grand societal challenges (Bernstein et al., 2021, 2022; Owen et al., 2021a; Stahl, 2022; von Schomberg & Blok, 2021), whether

and how RI could be integrated and the impact of RI integration still needs to be explored.

Furthermore, little is known about RI, its implications for policies and practices, and how it corresponds with regional policies, innovation, and entrepreneurship processes for increased societal impact (Owen et al., 2021a; Owen & Pansera, 2019). Broadly, theoretical and empirical studies on RI have focused little on regional policies, innovation, and entrepreneurship processes in firms. Consequently, more conceptual and empirical studies are needed to know about the operationalizability of RI in the innovation and entrepreneurship process of firms and the potential impact of RI practices to provide solutions to grand societal challenges with increased societal impact (Owen et al., 2021a; Rauch & Ansari, 2022).

Therefore, there is a need to better understand and explain RI, its implications for regional policies, operationalizability in innovation and entrepreneurship and the impact of RI practices on grand societal challenges with increased societal impact. The overarching research question ***'How does the RI approach facilitate regional policies and innovation and entrepreneurship practices in firms toward increased societal impact in healthcare and welfare services?'*** responds to these issues by exploring first RI and its implications for regional policies, second investigating the extent to which RI can be operationalised in the innovation and entrepreneurship processes in firms and finally exploring the impact of RI practices in the context of grand societal challenges-

healthcare and welfare services which is the research context of this thesis.

RI literature advocates the need for the good governance of regional policies, innovation and entrepreneurial practices to address grand societal challenges with increased societal impact (Owen, 2014; Owen et al., 2012; von Schomberg, 2011). Scholars argue that for the good governance of regional policies, innovation and entrepreneurship activities in firms and to result in desired outcomes with broader societal impact, their purpose, process and outcomes should be aligned and reflected continually (Jirotka et al., 2017; Owen et al., 2013a; Stilgoe et al., 2013). Literature also indicated that the RI approach could play a crucial role in steering the purpose, process and outcomes of regional policies, innovation and entrepreneurial practices to broader societal impact (Fitjar et al., 2019; Jakobsen et al., 2019; Owen et al., 2021a; von Schomberg & Hankins, 2019). However, a dearth of conceptual and empirical studies focuses on how RI facilitates the purpose, process and outcomes of regional policies, innovation and entrepreneurship practices in firms and, consequently, on their interactions for increased societal impact.

Accordingly, this thesis explores RI and its implications for regional policies, innovation and entrepreneurship practices. It contributes to the literature and calls for dynamic studies on the applied theoretical frameworks. The four research questions addressed in the four papers appended in this thesis explore distinct aspects of the overarching

question with different theoretical frameworks, which in combination, lead to a theoretical and empirical understanding of how RI in regional policies, innovation and entrepreneurship practices in firms could lead to increased societal impact.

As such, Paper I contributes to the ongoing debate on the role of RI in policies and practices in the governance of innovation and entrepreneurship to address grand societal challenges with increased societal impact (Owen et al., 2012; Owen et al., 2021a; von Schomberg, 2013, 2019). Furthermore, Paper I contributes to the debate on engaged pluralism through interdisciplinary studies (Fagerberg et al., 2013) by bringing RI and regional studies together. In so doing, Paper I shows the compatibility of RI and regional studies, their impact on each other and their synchronised effectiveness on regional development. At the same time, the purpose of regional policies seems to achieve sustainable regional development via competitiveness (e.g. Foray, 2014; Martin, 2012) and cohesion (e.g. Crescenzi & Giua, 2016; McCann & Ortega-Argilés, 2015), their emphasis is more on competitiveness and less on cohesion, questioning the sustainability of the regions. Paper I argues that since the RI aims at responsible governance of science, innovation and entrepreneurship policies and practices to align with the needs, values and expectations of the region for increased societal impact (Owen et al., 2012; von Schomberg, 2011), RI can be vital in shaping the purpose of regional policies to achieve overall regional goals. Furthermore, featured RI drivers, RI tools, RI barriers and RI outcomes

in Paper I indicated the operationalizability of RI in innovation and entrepreneurial policies and practices for desired responsible outcomes.

Papers II and III explore the viable approach to integrating RI dimensions in firms' innovation and entrepreneurship processes. While Paper II exclusively explores the inclusion dimension of RI in the innovation process, Paper III explores the integration of RI dimensions of inclusion, anticipation, reflexivity and responsiveness in the venture creation and firm development process.

Paper II investigates how firms integrate RI into the innovation process, specifically looking at the inclusion dimension of RI. The paper contributes to the debate on RI in the industry by bringing to the fore the role of RI in the innovation process, particularly in start-ups. The findings reveal that firms and entrepreneurs are unaware of RI and its dimensions of inclusion, anticipation, reflexivity, and responsiveness per se. This is consistent with previous studies on RI in the industry (Flipse & van de Loo, 2018; Long et al., 2020; Lubberink et al., 2019; Oftedal et al., 2019a; van de Poel et al., 2020). However, the findings indicate that firms and entrepreneurs integrate and practice RI to varying degrees during innovation, supporting their motivation and shifting towards the RI trajectory.

Furthermore, the findings support the challenges of adoption and practice of inclusion in corporate innovation indicated by previous studies on RI in the industry (e.g. Blok & Lemmens, 2015; Lubberink et al., 2017; van de Poel et al., 2020). However, the findings suggested that

by including stakeholders and users in the innovation process, firms and entrepreneurs could learn about the needs, concerns and expectations (Concannon et al., 2014; Marschalek et al., 2022; von Schomberg, 2011). Inclusion and face-to-face interaction facilitated communication of knowledge, especially tacit knowledge (Marschalek et al., 2022; Timmermans et al., 2020), enabling collaboration, user empowerment and co-creation of solutions (Oliveira et al., 2019; von Hippel, 2005; von Hippel & von Krogh, 2015).

Despite several challenges, the findings of Paper II revealed that well-managed inclusion from the designed phase of the innovation process enabled early need-solution interaction, facilitating firms to pivot early in the innovation process, saving resources and enhancing the organisational intelligence for the strategic move. Such initiation enabled them to innovate optimal desirable solutions. Nevertheless, inclusion provided broader anticipation of the opportunities and challenges from different viewpoints valuable for identifying and addressing potential adverse impacts, building trust and credibility with stakeholders, and staying on top of regulatory and legal obligations (Bacq & Aguilera, 2022; Marschalek et al., 2022).

Paper III explores how RI dimensions contribute to building firms' and entrepreneurs' opportunity confidence (OC) in new venture creation and firm development. By examining venture creation and firm development process in general and OC and the role of the RI approaches in identifying and evaluating venture ideas that might help build OC to act

for desirable outcomes, the paper contributes to the RI debate that RI should stem from exciting innovation and entrepreneurship practices and not an entirely new and complicated approach (Dreyer et al., 2017; Long & Blok, 2018; Martinuzzi et al., 2018; Stahl et al., 2017; van de Poel et al., 2020). Furthermore, it contributes to the debate that firms and entrepreneurs practice RI if they see the benefits of such practices (van de Poel et al., 2020). In doing so, the paper contributes to RI discourse by addressing the value of responsible entrepreneurship.

The findings indicate that despite some challenges of integrating RI dimensions to full scale in venture creation and firm development processes in the short run, it significantly impacts firms and society in the long run. Furthermore, the findings show how firms and entrepreneurs can assess their offerings' feasibility and scope through inclusion and develop OC about their products, service efficacy, and the feasibility of new ventures through anticipation and boosted belief of entrepreneurs and firms about the ventures and self-efficacy belief in venture creation and firm development. Furthermore, findings also revealed that such RI in the venture creation process enabled firms and entrepreneurs to co-design solutions and boost users' and stakeholders' confidence levels about their offerings, increasing the likelihood of adopting the products and solutions, trust and reputation.

Finally, Paper IV explores how a business organisation could pursue RI in business development and create solutions as innovation and entrepreneurial outcomes that are socially responsible and sustainable.

The paper also explores how organisational initiatives could contribute to addressing societal challenges and create a positive societal impact. Paper IV argues that although innovation outcomes are not known before they are brought into use, however, the possible negative impact that the products or services bear could be managed by integrating RI into the purpose and process of innovation and entrepreneurial activities (Bessant, 2013; Jirotka et al., 2017; Stahl et al., 2017; Stilgoe et al., 2013; von Schomberg, 2019).

Furthermore, the findings showed that competitiveness for organisational growth depends not on innovation or venture outputs but on their impact on stakeholders and society. However, there should be an organisational commitment to integrate and practice RI in innovation purpose, process and outcomes(Owen et al., 2021b) and support from institutions and stakeholders in the innovation and entrepreneurial ecosystem (Stahl, 2022). Findings also articulated that societal impact can be increased by the diffusion and scaling up of innovative solutions, which the sustainability of their innovation outcomes can ensure.

Overall, the thesis contributes to the debate on engaged pluralism through interdisciplinary studies (Fagerberg et al., 2013) by bringing RI, regional studies, innovation and entrepreneurship studies together and exploring their impact on each other and their combined impact on increased societal impact.

This thesis contributes to the debate on responsible innovation in health (Lehoux et al., 2018, 2023; Pacifico Silva et al., 2018; Silva et al., 2021).

Bringing to the fore the context of the healthcare and welfare service sector, one of the grand societal challenges, the thesis investigates the potential role of RI in this sector. Furthermore, the thesis relates digital innovation and entrepreneurship in the healthcare and welfare service sector to RI, as it raises the 'dark side' of innovation and entrepreneurial activities (Jirotka et al., 2017; Silva et al., 2021; Stahl et al., 2014).

6.2 Implications for practitioners and policymakers

6.2.1 Managing innovation for desirable outcomes which are sustainable and responsible

As discussed, based on the thesis findings, harnessing the potential of innovation and entrepreneurship to achieve overall regional goals lies in the purpose, process and outcomes of innovation and entrepreneurial activities. Also, there should be responsible interactions and commitments from practitioners and stakeholders in the innovation and entrepreneurship ecosystem.

In this regard, this thesis's practical implications would provide managers and entrepreneurs with new insights into knowledge acquisition and communication of tacit knowledge, establishing and maintaining knowledge networks, and acquiring resources essential for innovation success. Furthermore, managers and entrepreneurs will be able to identify which mode of stakeholder engagement is suitable at what stage of the innovation process. They will be able to identify potential solutions through early need-solution interaction with users and stakeholders in the

innovation ecosystem. Accordingly, they can manage uncertainty about innovation acceptance by users and stakeholders.

Anticipating their solutions' intended and unintended impacts on users, stakeholders, and society, managers and entrepreneurs can reduce the socioeconomic, socio-ethical, and socioecological risks associated with their offerings, enabling sustainable, responsible, and desirable solutions for societal challenges.

The complex nature of grand societal challenges and issues of technoscientific approach or traditional problem-solving approach in addressing such challenges are presented in Paper II, appended in this thesis. The paper argued that such an approach and their inability to address societal challenges increases innovation success uncertainty due to stakeholders' and users' different needs and expectations. Thus, managers and entrepreneurs can integrate RI dimensions in their innovation process to facilitate the governance and management of innovation for need-based solutions. Such solutions are inclusive, sustainable, and socially responsible.

6.2.2 Developing opportunity confidence for venture creation and firm development

Paper III, included in this thesis, holds practical implications for new venture creation and firm development, specifically in the context of grand societal challenges such as healthcare and welfare services.

While entrepreneurship studies have long advocated opportunity as the core of entrepreneurship, opportunity confidence could be more appropriate in explaining entrepreneurial success. From the findings and insights presented in Paper III, managers and entrepreneurs can adopt the RI approach in developing opportunity confidence for new venture creation and firm development. The findings suggest that the RI approach enables firms to acquire the knowledge, expertise and resources necessary to boost their confidence to act, justify their actions, and create trustworthy relationships with stakeholders and potential users in the entrepreneurial ecosystem. Such initiation facilitates them in advancing firm development.

6.2.3 Managing innovation and entrepreneurial activities for sustainable growth and positive social impact

How the organisation grows and creates an impact on society depends on strategic decisions and managerial skills. Establishing dynamic capability, a trustworthy relationship with stakeholders and users, and brand image are components for boosting organisational growth. Therefore, managerial and strategic decisions should focus on selecting

projects and managing innovation and entrepreneurship for value creation rather than extraction. The insight presented in Paper IV of this thesis provides some fundamental approaches through which managers can access personal and organisational efforts to create and increase positive social impact. The social impact assessment framework developed adopting the RI approach in innovation and business development in the paper can be useful for managers and entrepreneurs to self-evaluate and reflect on their social impact and organisational performance.

6.2.4 Policy implications

The concept that research and innovation should benefit society is becoming more prominent. It is acknowledged that policy plays a vital role in driving innovation and entrepreneurial activities in regions. This thesis's findings hold implications for corporate research and innovation policy and policy for government research and innovation programmes. Governments and policymakers in the regions are concerned with the growing negative externalities such as socioeconomic, socio-ethical and socioecological issues due to economic activities, including innovation and entrepreneurship activities in regions. These issues must be addressed proactively for sustainable regional development of the regions. The paper I appended to this thesis highlighted that RI integration in regional policies and innovation, and entrepreneurship activities could be a viable approach. While formulating regional policies, innovation and entrepreneurship policies for regions,

policymakers should consider the purpose, process, and outcomes of policy implications.

Furthermore, it is important to make policy decisions based on interactions and collaboration with stakeholders at the micro, meso, and macro levels and firms in the region's ecosystem. Government innovation and entrepreneurship programmes and innovation and entrepreneurship policies should be coherent on the purpose, process, and outcomes of policy initiatives to achieve overall regional goals. Based on the results of Paper I, it can be concluded that regional policies have a clear purpose. However, the policy should be focused more on the process and anticipated outcomes of the policy's initiatives. Regional policies and innovation and entrepreneurship policies should focus on incentivising research and innovation targeting grand societal challenges.

Despite firms' and entrepreneurs' motivation to align the innovation and entrepreneurial activities towards RI aspects, and despite the significant role of RI in facilitating engagement in socially desirable, sustainable and responsible outcomes with increased impact, RI and its aspiration are not well embedded in the business community. Therefore, policy initiatives to promote RI in the business community are recommendable.

Furthermore, firms and entrepreneurs lack managerial skills to manage RI practices, hence the RI adoption and implementation dilemma in their activities. Therefore, regional and national policies must support and encourage small firms and entrepreneurs to stimulate inclusion and RI approach in innovation and entrepreneurship. Additionally, government

agencies and policy initiatives should focus on educating and training entrepreneurs to make a difference. Also, the thesis's purpose, process, and outcomes frame can be helpful tools when deciding on the policy instruments targeting grand challenges. Furthermore, it can be a helpful tool to assess the impact of funding allocated to innovation and entrepreneurship projects.

6.3 Limitations and suggestions for future research

Although this thesis provides some steps toward harnessing the potential of digital innovation and entrepreneurship to address the current and future healthcare and welfare services, this thesis is not without limitations. These limitations set the stage for further research.

The chosen research approach gathered valuable insights into the responsible innovation process in one particular sector and region. Despite this, the findings' generalisability is limited due to the study's geographical and sectorial scopes. Although the results may be transferable to other contexts, they may not be universally valid and directly transferred. Additionally, regions represent fragments of contexts with general governance structures, but they differ in their regional culture, healthcare and welfare systems, knowledge flow, values, and expectations. To make the findings of the study generalisable, further studies on comparative cases between regions in the context of digital healthcare and welfare services are required.

The thesis attempted to create a balanced picture of the phenomenon by employing a triangulation strategy and facilitating cross-validation. However, the papers in the thesis did not include data from end-user perspectives. Furthermore, though the study's context is healthcare service, the study does not include a hospital setting. It could be another research on its own. Therefore, these limitations open opportunities for future research.

Future research should seek insight from other regions, contexts, and industries related to digital innovation and entrepreneurship for further conceptualisation and advancement of theoretical frameworks for greater transferability and generalisation of the findings.

The other limitation of the thesis relates to the limited timeframe and limited access to the data collection. Paper I presented the conceptual development of RI and its implications for regional development through a systematic review of the literature on RI. However, the time constraints limited the study only to conceptual papers. Furthermore, the research would have been more robust if it could have included empirical papers to get a detailed overview of RI and its development. Similarly, the empirical data collected could not include hospital settings due to difficulty accessing and project timeframe.

When this study began, the empirical literature on RI in the industrial context was minimal. Most empirical studies focused on research projects (Bernstein et al., 2021). Future research can consider including

empirical studies, specifically RI, in the industrial context to provide operational insight into RI in the industry.

Papers II and III examined start-up firms in their early stages of innovation and venture creation processes. Hence, in most cases, the effects of innovation and entrepreneurial activities were too early to be known. Furthermore, the duration of such effects can be unpredictable.

This prevented us from concluding that any connections existed between exercising RI practice and its consequences for firms and society. More longitudinal studies would shed light on whether and to what degree practising RI influences firms' entry into the market with innovative solutions. Future research could address these limitations and contribute to theory, practice, and policy.

Paper IV, appended in the thesis, is based on a single case of a firm. A single case study design provided rich and detailed findings about RI practices and their implications for societal problem-solving and organisational growth in healthcare and welfare services. Nevertheless, the focus on RI practices in one context renders the findings not generalisable in other contexts. Further research adopting a multiple and comparative case study design could increase the generalizability of the findings.

Furthermore, out of three established firms in this study, one has started digital healthcare as a separate business unit, one focuses on installing digital technology into existing products as incremental innovation, and only one has entered global markets. Therefore, this study could not

include the outcomes of the products/services and their impact on contributing to overall healthcare and welfare services challenges. Future studies should focus on fully implementing digital technologies in healthcare and welfare services. Since most of the firms in the study are still developing and testing the solutions, the impact of their implementation on healthcare and welfare services is still to be uncovered. Future studies should follow these firms and see how they manage organisational sustainability and create a broader impact.

6.4 Concluding remarks

This thesis has indicated that RI in regional policies, innovation and entrepreneurship practices bear the potential to govern regional policies, innovation and entrepreneurship as per the needs, values and expectations of the region in the context of grand societal challenges with increased societal impact. However, RI and its aspiration can only be achieved if its dimensions are well integrated into regional policies, innovation and entrepreneurship practices. The thesis also indicated that RI does not need to re-invent the wheels again; it can be integrated into the existing corporate innovation and entrepreneurship activities.

However, to achieve the overall aims of RI and the region, policies and practices' purpose, process, and outcomes should be aligned and reflected continuously. Furthermore, the success of RI integration in practices relies on the commitment of firms and stakeholders in the innovation and entrepreneurship ecosystem. Such initiation leads to the

innovation of need-based solutions that are desirable, sustainable, and responsible, eventually contributing to the grand societal challenges.

Although RI can influence the purpose, process, and outcomes of regional policies, innovation and entrepreneurship practices in firms, especially start-ups with limited resources and networks, find it challenging to adopt and practice RI in corporate activities. The case studies revealed that firms and entrepreneurs are concerned about society and showed their motivations towards the RI trajectory. However, they require supportive mechanisms to overcome their challenges while corresponding with RI in their corporate activities.

Altogether, the thesis contributes to and extends the discussion on the integration of RI in innovation and entrepreneurship by providing new evidence on the relative importance of RI in aligning and reflecting on the purpose, process and outcomes of innovation and entrepreneurship policies and processes. Furthermore, the thesis contributes to theory, practice and policy. Theoretically, it adds knowledge of the applicability of RI in regional policies and firm practices. At a practical level, the thesis provides nuanced insights to integrate RI into the purpose, process and outcomes of regional policies and practices, including innovation and entrepreneurship policies and practices to promote overall regional goals. Finally, the thesis makes some policy suggestions and highlights limitations and avenues for future research.

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Appendices

1. Appendix A1: Interview guide (Firms)

Baseline questions

1. Can you tell us about the product or service you offer in your department, company or organization? Years in business, employee numbers.

Novelty

1. Is the product/solution groundbreaking or new? Please elaborate.
2. Is the product a simplification of an existing solution or solutions?

Inclusivity

1. How did you understand what was important to the user – what makes you understand what is important?
2. Was there anyone else who made you change your view? How did this happen?
3. Who did you first include when you started thinking about the idea? Why this person?
4. Do you consciously decide who you include in product development? What are your criteria for inclusion?
5. How important is the user for you in the development of the product or service?

Reflexivity

1. What was your motivation for this product/service when you started, and what is your driver now?
2. What was the problem you were trying to solve?
3. Did you overthink anything?
4. Was there anything you wasted a lot of time on?
5. What was your original plan for the commercialization? How did your reflections change the way the product was commercialized?
6. To what extent is there room for reflection in the company's daily operations?

COST STRUCTURE

1. What are the most important costs in your business model?

KEY RESOURCES

1. Which key resources does your value proposition require
   - Physical resources (ex?)
   - Intellectual resources (ex?)
   - Human resources (ex?)
   - Financial (ex?)

KEY PARTNERS and Suppliers

1. Who are your key partners?
2. What are the main attributes that you consider when you want to enter a partnership?

3. What are your partners' roles in the ultimate value that you want to deliver with your product?
4. Who are your key suppliers?
5. How do you select your suppliers?

Responsiveness to stakeholders and external and internal factors; responsiveness to negative consequences.

1. Who are your stakeholders – can you describe them?
2. Is there room for change based on input from customers, users, or other stakeholders? (How have the stakeholders been involved?)
3. Has the idea changed in relation to the initial plan based on stakeholder input? (Describe)
4. At what stage (beginning, later) was it important to include users? And why at this stage?
5. Do you receive praise from stakeholders for the way you interact with them?
6. Do stakeholders agree with what your product is trying to do?

Product development process

1. What stage of the product development process are you in (pre-product launch, launch, or production)?
2. How long will or did it take to complete product development?

Anticipation

1. What is the consumers' expectation of the product/solution?
2. Will the solution/product help solve a societal problem? (Describe)
3. Can you describe the ideal social impact of the product?

4. Did you develop the product/solution you intended to create? If you didn’t, what did you envision to be the ideal solution to be? What were your assumptions about that product/solution?
5. Who did you envision your customer/user to be initially? Did it differ? How?
6. What economic/social challenges/obstacles did you experience? Was this different from what you initially thought?
7. Was the problem that you aimed to solve different than what you expected?
8. Can you tell us something that really surprised you about the product/service?

Responsibility

1. How important is it for you to follow the community's formal and informal rules and laws?
2. How important is it for you to respect the thoughts and ideas of others?
3. How important is it for you to take responsibility for the community's concerns?

CUSTOMER SEGMENT

1. Who are your most important customers? And what characterizes them?

VALUE PROPOSITIONS

1. For whom is your company creating value?
2. What value do we deliver to the customer?

3. Considering different customer segments, how do you relate your product's value to their needs?

CHANNELS

1. Through which channels do you reach your customers?
2. How do you reach them?
3. How are the channels integrated?
4. Which ones work best?
5. Which are most cost-efficient?

CUSTOMER RELATIONSHIP

1. How do you maintain the relationships with your customer segments over time?
2. Have the customers been part of the process (inclusiveness, etc.) of implementing RI principles
3. How did this affect the success of your firm?
4. What ethical and moral considerations are important in your customer relationships?
5. Taking an example of an existing customer, what might make him/her satisfied and loyal to your product/service?
6. Have you experienced your customer(s) stopping to buy your product/using your service? Do you know the reasons? Did they choose another product/service?

REVENUE STREAMS

1. For what are the customers currently paying?
2. How do you manage the tension between what customers are willing to pay and your desired pricing?
3. How are they paying?

Early market success

1. How satisfied are you with the sales of your product/service?
2. How satisfied are you with the income you have received from sales of your newly developed product/service in relation to the time, resources, and efforts you used to create it?
3. Do you feel that your product/service is a success? If we ask you to rate it from 1 to 10, with 1 being a failure and 10 being super success, what rate would you give?
4. Are you satisfied with the increases in sales? With profits?

2. Appendix A2: Follow-up interview guide (Firms)

Changes

What has changed since the last time we talked?

What was the reason behind the change?

Was the change about:

- Product/ Service?
- Market?

Or the business model?

- Value proposition?
- Distribution channel?
- Customer group?

Who was involved in the decision to change?

What were the opportunities and challenges you encountered during this period?

How did you overcome the challenges?

3. Appendix A3: interview guide (Stakeholder/NSCC)

1. Could you please give us a brief history of NSCC (when was it established, what are its projects, etc.)?
2. What is the main purpose of establishing this cluster? Why the healthcare and welfare sector?
3. How do you select members in the cluster? Criteria?
4. How do you make decisions?
5. Who are on the decision board?
6. Who is responsible for what?
7. What are the roles of members? What are their responsibilities?
8. Which major factors do you think affect innovation in this region? How are you managing them?
9. How do you coordinate interactions among members?
10. What are your plans to promote innovation?
11. What are the current projects or activities, and what is the plan for the future?
12. How do you evaluate the status of a cluster? Success or failure rate?
13. Who takes responsibility if innovation succeeds/fails?
14. Could you please explain the plans for the future promotion of innovation in the region?

4. Appendix A4: interview guide (Public funding bodies)

1. How do you prioritise the project for funding?
2. What are the primary objectives of providing support?
3. Who decides which project to support with funding?
4. How do you evaluate the impact of funding?
5. What kind of support do you provide for the firms/ entrepreneurs?
6. How do you access the impact of innovation outcomes?

5. Appendix A5: interview guide (Experts)

1. What kind of innovation do you think is necessary in this region?
2. In your opinion, what kind of research and innovation should be prioritised in the region?
3. Who do you think should be responsible for innovation and entrepreneurial activities?
4. In your opinion, what should be the overall objectives of innovation and entrepreneurial activities?
5. How do you motivate young entrepreneurs in the region?
6. What advice would you like to convey to the business community in the region?

6. Appendix A6: interview guide (Healthcare experts)

1. What are the major challenges in healthcare services in this region?
2. Could digital technology be a potential solution for addressing healthcare challenges?
3. How satisfied are you with the current approach in the healthcare system?
4. How do you think this sector can be improved/ made better?
5. Are there any alternative solutions that can be brought into action to address the healthcare challenges?
6. How do you see the healthcare service situation 5 or 10 years from now?
7. What role should the business community play in the healthcare service sector?
8. Who decides what kind of healthcare service solution should be implemented?

PART 2: *Research Papers*

1. Responsible research and innovation: a systematic review of the literature and its applications to regional studies
   -Raj Kumar Thapa, Tatiana Iakovleva and Lene Foss

2. Governing digital innovations for responsible outcomes – the case of digital healthcare and welfare services
   -Raj Kumar Thapa and Tatiana Iakovleva

3. Responsible innovation in venture creation and firm development: The case of digital innovation in healthcare and welfare services
   -Raj Kumar Thapa & Tatiana Iakovleva

4. Responsible Research and Innovation: Innovation initiatives for Positive Social Impact
   -Raj Kumar Thapa & Tatiana Iakovleva

Paper I

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Responsible research and innovation: a systematic review of the literature and its applications to regional studies

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Responsible research and innovation: a systematic review of the literature and its applications to regional studies

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ABSTRACT

While innovation should be about socioeconomic transformation of society, concerns have been raised about its negative externalities including growing disparities within and between regions. Arguably, Responsible Research and Innovation (RRI) offers a potential solution to address these concerns. However, in theory, its conceptualization and operationalization remain ambiguous. Further, in practice, this makes its application to regional development difficult. Accordingly, this study first conducts a systematic literature review of conceptual papers on RRI. It identifies themes and categorizes them into four domains: drivers, tools, outcomes and barriers. Second, these domains are applied to regional innovation studies. The paper contributes to an increased understanding of RRI and its applications to sustainable regional development as well as how RRI and regional innovation studies can benefit from each other.

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Responsible research and innovation; systematic literature review; stakeholders; region; policy; regional development

1. Introduction

The purpose of innovation should be in and around socioeconomic transformation and overall development of society. However, current trends in research and innovation have raised social, ethical and environmental concerns (Owen, Bessant, & Heintz, 2013). While this applies globally, the same can be taken at a regional level. In particular, there are concerns that at the regional level, innovation and related economic activities are leading to growing disparities between and within regions producing winners and losers (Rodríguez-Pose, 2018; Storper, 2018). These issues should be addressed proactively to ensure that society obtains the greatest benefits from science, research and innovation and ensures sustainable development.

Responsible innovation (RI) and responsible research and innovation (RRI)[1] have been gaining in currency as important themes in recent years (Stilgoe & Guston, 2017). The discussion of ethics in science, technology, research and innovation is not new, but the concept of RRI appeared recently to incorporate responsibility into research and

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innovation policies and practices (Flick, 2016; Owen, Macnaghten, & Stilgoe, 2012; Stilgoe, Owen, & Macnaghten, 2013; Von Schomberg, 2011). RRI has emerged at the wake of several grand societal challenges and declining public trust on government, businesses, science and innovation (EBT, 2017). The aim is to restore public confidence in science and innovation (Owen et al., 2012), to achieve inclusive and sustainable future (Stilgoe et al., 2013) through societal desirable innovation (Von Schomberg, 2011).

According to Von Schomberg (2011, p. 9), RRI is defined as 'a transparent interactive process where societal actors and innovators become mutually responsible to each other, viewing the ethical acceptability, sustainability and societal desirability of the innovation process and its marketable products'. In 2013, Stilgoe and colleagues proposed a broader definition of RRI 'taking care of the future through collective stewardship of science and innovation in the present' (Stilgoe et al., 2013, p. 1517). RRI also refers to the democratic governance of the purpose of research and innovation and the orientation of that research and innovation towards the production of the 'right impact' (Owen et al., 2012; Weckert, Valdes, & Soltanzadeh, 2016). This implies inclusion of stakeholders and the public at the very beginning of the research and innovation process to collectively direct it to generate the 'right' outcomes in favour of people, the planet and profit (Illies & Meijers, 2009; Sutcliffe, 2011).

The above developments and emergence of RRI have implications for regional development. Economic activities and innovation can be viewed in the space context (Boschma & Martin, 2010) and should be targeted towards solving major social and regional problems. The regional innovation system literature (e.g. Asheim, 2000, 2004; Morgan, 2007), as well as open innovation literature (Chesbrough, 2006) and regional entrepreneurial ecosystems literature (e.g. Feldman, 2014) has put an emphasis on the presence of a variety of actors including users in the innovation process. However, these scholars have taken the governance of innovation as given. Thus, the negative externalities of economic activities including innovation are often overlooked in these debates (Martin, 2016). Yet, there is evidence of increasing disparities between and within regions due to unequal distribution of gains within them (Iammarino, Rodríguez-Pose, & Storper, 2019; Rodríguez-Pose, 2018; Storper, 2018). Therefore, RRI brings to the fore the importance of governance of the innovation process, particularly the inclusion of stakeholders to allow both top-down and bottom-up processes as well as the need for inclusive and sustainable development, specifically in the context of regional development.

In the European context, in particular the EU, RRI has emerged as a topical policy issue (Coenen, 2016; European Commission, 2013; Fitjar, Benneworth, & Asheim, 2019; Rip, 2014). At the same time, there has been ongoing discussion and debate on sustainable regional development through different policy instruments such as the Cohesion Policy (Bachtler, Martins, Wostner, & Zuber, 2017). Thus, while the competitiveness of regions (Foray, 2014; McCann, 2008) are essential for economic growth, employment and profitability, their social cohesion (Barca, McCann, & Rodríguez-Pose, 2012) equally matters. It seems, on the one hand, the focus of regional innovation policies is still more on competitiveness and less on cohesion. On the other hand, the emphasis on RRI, particularly looking at Horizon 2020 (European Commission, 2014), a European research programme, has been more on governance broadly but less on its specificities. Both these situations and competing demands on economic competitiveness and social

cohesion put into question the essence of regional development, whether a balance can be found and how.

In this context, RRI could be a viable approach for sustainable regional development, taken into consideration its implications for regional innovation policy and practices. However, how or to what extent can responsibility be conceptualized and operationalized within the field of innovation studies as well as applied to regional development remains ambiguous (Forsberg et al., 2015; Owen et al., 2012). At the same time, in view of the need for engaged pluralism through interdisciplinary studies (Fagerberg, Martin, & Andersen, 2013), there is a lack of studies that have looked at both RRI and regional innovation studies together. As such, little is known about how much RRI can learn from regional innovation studies and vice versa. Therefore, this study seeks to answer the following research questions:

> How is RRI conceptualized in literature? And, to what extent can it be applied to the context of regional development and vice versa?

Accordingly, this study has two aims: first, it explores the concept of RRI through systematic literature review and identifies emerging themes. Second, it applies these themes to regional innovation studies as well as reflect on how the latter can also enhance the theory on RRI. The study makes a contribution by bringing RRI and regional innovation studies literature together. The rest of the paper is structured as follows: Section 2 introduces the method used for the systematic literature review. Section 3 presents descriptive analysis and Section 4 presents a thematic analysis of the literature on RRI based on the SRL. Section 5 is the discussion, synthesizing the four domains of the themes on RRI and their application to regional development. Section 6 concludes with a summary discussion including implications for theory, practice and policy, and avenues for future research.

2. Method

We followed the SLR procedure of Tranfield, Denyer, and Smart (2003). A literature search[2] in the Web of Science, Science Direct, Springer, Scopus and Emerald databases was conducted in order to cover RRI research across all disciplines.[3] In addition, papers from *The Journal of Responsible Innovation*[4] were also included in the analysis. Papers were extracted from the databases using the following search terms, either alone or in combination, using the logical operators 'AND' and 'OR': 'responsible innovation' and 'responsible research and innovation', from the period 2003–2016. We chose to start our search in 2003 as the concepts of RI and RRI rapidly became the focus of debate and discussion across intellectual and institutional discourses from the mid-2000s onwards (Stilgoe & Guston, 2017). Moreover, the term 'responsible research' first appeared in the European Commission's Sixth Framework Program in 2002 ("The 6th Research Framework Programme (FP6)," 2005) with the notion of creating greater public engagement with science and technology. There has been a growth in publications of academic literature on RRI since then, as signified by the launch of *The Journal of Responsible Innovation* in 2014.

The search results were exported into EndNote and, duplicates papers were removed and the accessibility of the full texts was investigated. Papers for which only abstracts

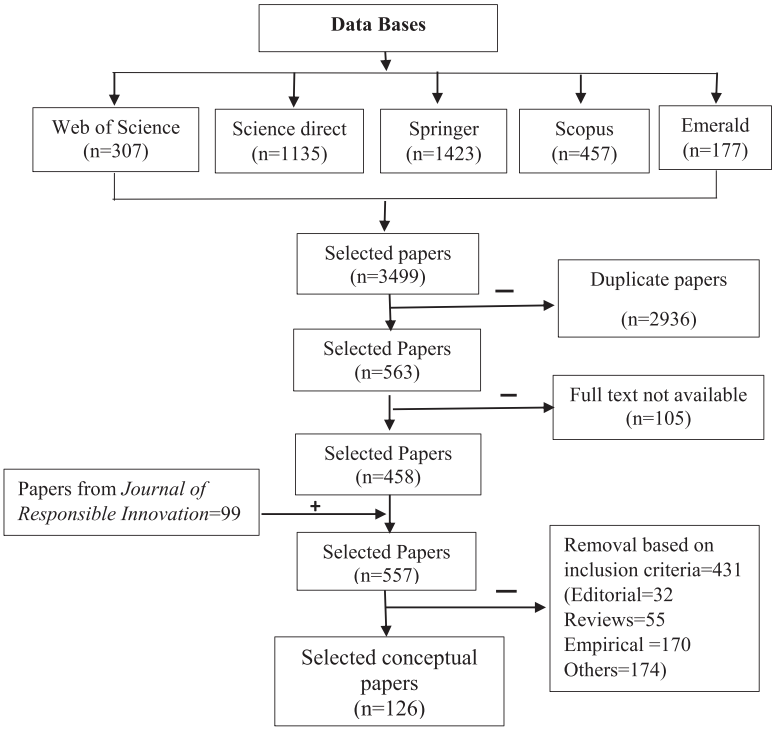

Figure 1. Flow chart of SLR process.

were available were eliminated from the study. The available full texts papers were categorized as either editorials, reviews, conceptual papers or those that were empirical in nature. Only full-text conceptual peer-reviewed academic articles published in English during the period 2003–2016 were included. Figure 1 describes the selection process.

We followed the recommendation of Thorpe, Holt, MacPherson, and Pittaway (2005) to adhere strictly to the principles of transparency, clarity and broad coverage of the discussion of RRI in our study. A total of 126 papers were analysed in this study. Each author reviewed the full text of one-third of the articles and analysed them in accordance with the reading guide developed by the authors (Appendix 1). The reading guide included the review of key themes, theories and contributions towards theory and practice.

After the initial review, we deduced the major themes of the papers from the key concepts, discussion, principles, ideas, etc. presented within them. 'Themes' are defined here as fundamental concepts that describe the subject matter, core ideas, concepts, discussion and conceptual linkage of expression represented in the articles (Ryan & Bernard, 2003; Thorpe et al., 2005). We created additional tables, not included in the current paper version due to space limitations, where a description of each 'theme' by each article was clearly specified. To illustrate, we saw following definition of engagement in work of Vincent (2014) 'Public engagement in science and innovation to make a shift from "deficit model" to a "participatory model" to make public presence in scientific enterprise'. In Gudowsky and Peissl (2016), authors talk about 'Public engagement in future studies to

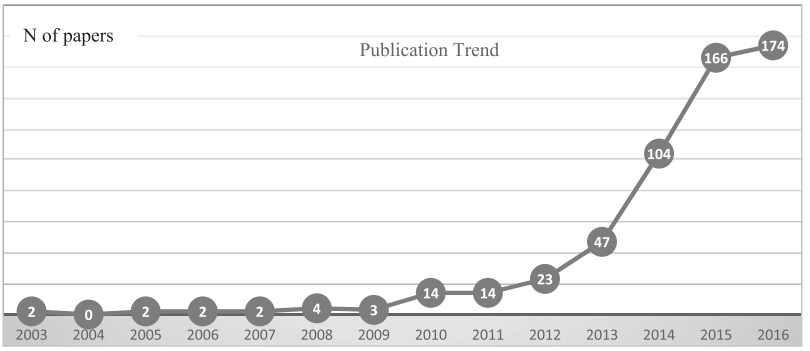

Figure 2. Numbers of paper by year of publication.

Table 1. List of journals publishing most RRI papers.

Journal	Number of papers	%
Nanoethics	15	11.9
Journal of Responsible Innovaiton	15	11.9
Science Engineering and Ethics	11	8.73
Life Sciences, Society and Policy	5	3.96
Futures	5	3.96
Technology in Society	5	3.96
Technology Forecasting and Social Change	4	3.17
Journal of Information, Communication and Ethics in Society	4	3.17

reflect public values as per societal needs', and Malsch (2015) mentions the need to 'Strengthen democratic right of individuals including government officials, members of civil society organizations, and employees of companies'. These articles were then seen as addressing the themes of 'public engagement', 'stakeholder engagement'. During our analysis, we identified also other themes, like upstream engagement, transdisciplinary approach, that together with pre-engagement, stakeholder and public engagement were labelled 'RRI-drivers' domain. Such an approach to categorization and labelling is suggested by (Braun & Clarke, 2006; Jones, Coviello, & Tang, 2011).

3. Descriptive analysis

A total of 557 papers were identified on the topic of RRI, including theoretical contributions, editorials, reviews, empirical studies and other types of paper. These papers are published in 208 different journals,[5] which illustrates that the topic of responsible innovation has spread across different domains and disciplines. Until 2009, only a limited number of publications existed but this tripled between 2013 and 2015. Figure 2 gives an overview of the evolution of the field based on the distribution of the 557 papers between 2003 and 2016.

The 126 conceptual papers subjected to analysis in this paper are spread across 57 journals (Appendix 2). Table 1 presents an overview of the major journals that publish the majority of conceptual RRI papers.

As evident from Table 1, discussion about RRI is widely spread across disciplines. The majority of RRI research is concentrated in and around sensitive areas of technological

Table 2. Thematic areas and domain categorisation of papers with corresponding authors.

Domains	Thematic area	Authors
RRI-drivers (28 articles)	Pre-engagement	te Kulve & Rip, 2011
	Stakeholder engagement	Schwarz, 2009; Rose, 2012; Malsch, 2015; Nathan, 2015; Pols, 2016; Allon et al., 2016; Gudowsky & Peissl, 2016; Schroeder et al. 2016
	Upstream engagement	Lee, 2012; Torgersen and Schmidt, 2013; Bronson, 2015; Patrignani & Whitehouse, 2015b
	Public engagement	Hilstrom, 2003;Rose et al., 2011; Stilgoe, 2012; Pierce, 2013; Vincent, 2013c; Guston, 2014; Hester et al., 2015; Gudowsky & Peissl, 2016; van der Burg, 2016
	Civil society engagement	Allon et al., 2016; Paredes-Frigolett, 2016
	Transdisciplinary	Prónay and Buzas, 2015; Siemieniuch et al., 2015; Clarke and Kitney, 2016; Turcanu et al. 2016
RRI-tools (57 articles)	Walkshop approach	Wickson et al., 2015
	Engagement workshop	te Kulve & Rip, 2011; Blok, 2014; Selin, 2015; Stahl & Coeckelbergh, 2016; Rerimassie, 2016
	Online platform/Online knowledge sharing opening up	Selin, 2015; van Oost et al., 2016 Jakobsone and Cakula, 2014; Vogel, 2014; Rose, 2012; Gupta et al., 2016
	Comprehensive and acceptability analysis	Patenaude et al., 2015; Meissne et al., 2016
	Social experimentation	Stilgoe, 2012; Stilgoe, 2016
	Foresight	Stahl, 2013b; Vincent, 2013d; Guston, 2014;Gudowsky & Peissl, 2016; Rhisiart et al., 2016;
	Hermeneutic	Grunwald, 2014
	Anticipation (of risk)	Hilstrom, 2003; Som et al., 2010; Owen et al., 2012; Vincent, 2013a; Guston, 2014; Wender, 2014; Hester et al., 2015
	Technology assessment	Rip, and van Lente, 2013; Schaper-Rinkel, 2013; van Oudheusden, 2014; Fuchs and Gazso, 2015; Kiran et al., 2015; Le Feuvre et al., 2016; Ingelbrecht, et al. 2016
	Informed consent	van Veen, 2013; Kelin, 2015; Flick, 2015; Spruit et al. 2016; van de Poel, (2016)
	Governance (by experimentation)	Asveld, 2016; Laird, and Wynberg, 2016
	Participatory appraisal	Jahnel, 2015
	Socio-technical integration	Fisher et al., 2015; Stahl et al., 2014; Carayannis et al., 2016; Saez-Martínez et al., 2016; Turcanu et al., 2016
	Design strategy	Wildman, 2007; Timmermans et al., 2011; Kiran, 2012; Stahl, 2014; Marie et al., 2015; Pesch, 2015; Woo et al., 2015
	Action research	Goorden etlal., 2008
RRI-outcomes (54 articles)	Lifecycle thinking	Kohler, 2013; Wender et al., 2014; Patrignani and Whitehouse, 2015b; Thorstensen, and Forsberg, 2016
	Attitude of prudence	Vincent, 2013b
	Responsible attitude	Voegtlin & Scherer, 2015; Vincent, 2013a; Sthal, 2013a; Blok, 2016; Peterson and Wickson, 2016
	Goal oriented responsibility	Patrignani, and Whitehouse, 2015a
	Responsiveness	Owen et al., 2012; Blol, 2014; Mampuys, and Brom, 2015; Clarke and Kitney, 2016; Gupta et al., 2016
	Alignment and harmony	van der Burg, 2010
	Mutual understanding and respect	Blok, 2014; van der Meij, 2015; Gupta et al., 2016
	Trust	van Veen, 2013; Haen, D. 2014; Asveld, 2016; Turcanu et al., 2016
	Sustainability impact	Owen et al., 2012; Davis and Laas, 2014; Voegtlin & Scherer, 2015; Schroeder, and Ladikas, 2015; de Saille & Medvecky, 2016
	Shared responsibility	Malsch, 2015
	Glocal sustainability	Deblonde, 2015, Pelle' and Reber, 2015
	Consensus	Stahl, 2014; Struik et al., 2014; Fuchs and Gazso, 2015; Marie et al., 2015; Hagen, 2016; Stahl & Coeckelbergh, 2016
	Co-creation	Wickson et al., 2015; Selin, 2015; Mavroeidid and Tarnawska, 2016
	Quality of life	Peine et al., 2015
	Social progress Sharing economy	Roco et al., 2011; Stahl & Coeckelbergh, 2016; Venot, J.P (2016), van den Hove et al., 2012; Rip, 2014; Ziegler, 2015; Moraglio and Dienel, 2015

(*Continued*)

Table 2. Continued.

Domains	Thematic area	Authors
	Integrity	Gardner and Williams, 2015; Horn, 2016; Lacour et al., 2015
	Care	Pavie, 2014; Preston and Wickson, 2016
RRI-barriers (20 articles)	Principle-based decision-making	Holbrook & Briggle, 2014; Wiesing and Clausen, 2014; Pols, 2015
	Asymmetrical power distribution	Tyfield, 2012; Saravanamuthu et al., 2013; Forsberg, 2014; van Oudheusden, 2014
	Moral pluralism	Pelle', 2016; Wong, 2016
	Conflicting interests	Fouilleux and Loconto, 2016; Taddeo, 2016; Weckert et al., 2016
	Over inclusiveness	Spinello, 2003
	Multiple values	Racine et al., 2014; Zwart et al., 2014; Arnaldi & Gorgoni, 2015; Mampuys and Brom, 2015; Ruggiu, 2015
	Level of perceived responsibility	Grinbaum, 2013
	Volitional evolution	Miller, 2015

innovation such as nanotechnology, biotechnology, gene-drive technology, digital technology, etc.

4. Thematic analysis

This section addresses the first research question: How is RRI conceptualized in literature? Accordingly, we endeavour to understand the conceptualization of RRI within regional innovation studies and other related fields as well as extend its potential applications to regional development. We therefore, subjected the included papers in the study to thematic analysis and identified themes, which we categorized into four RRI-domains as: drivers, tools, outcomes and barriers.

The thematic areas and domain categorization of the papers included in this study, together with their authors, are presented in Table 2. Some articles address two or more domains, and are therefore included in each of them.

In general, RRI is conceptualized as collective stewardship of science and innovation in order to meet the needs and expectation of society and to ensure inclusive, responsible and sustainable development. Specifically and evident in Table 2, the most debated domains of

Table 3. Major themes on RRI-drivers and description.

Thematic area	Description
Public engagement	Public engagement in science and innovation to make a shift from 'deficit model' to a 'participatory model' to make public presence in scientific enterprise.
	Public engagement in future studies to reflect public values as per societal needs.
Stakeholder engagement	Societal actors (researchers, citizens, policy-makers, third sector organizations and businesses) work together during the whole research and innovation process to better align both the process and its outcomes with the values, needs and expectation of society.
	Stakeholder engagement for communitarian and subsidiarity perspectives.
	Strengthen democratic right of individuals including government officials, members of civil society organizations and employees of companies.
Upstream engagement	No guarantee that the responsibility will eliminate risk in condition of uncertainties. By the process of upstream engagement, the purpose is to create an environment of shared responsibility.
	During public debate, agenda should be kept open even if this result in a conflict, such conflict in fact would be best stimulus for further debate.
	Means of including wide variety of voices and values that could help in shaping research and innovation attuned with the values of wider community.
Transdisciplinary	Means for dealing with prospective limitation of scientific knowledge and technological know-how.

RRI are tools, followed by outcomes, drivers and RRI-barriers but the last has received limited attention. Below we discuss each domain in more detail.

4.1. RRI-drivers

The key themes within this domain focus on the antecedents or elements that lead to RRI. These elements mainly reflect the way in which RRI can be approached and represent the basic conditions necessary for RRI. What drives RRI is engagement, in particular the engagement of users, customers, relevant stakeholders, experts, policymakers, politicians and the public in the early stage of the research and innovation process by way of active and deliberate participation. Although different themes appear within this domain, the bottom line is the inclusion of different actors in research and innovation activities. This adds a diversity of knowledge and better anticipation of consequences of the result of basic or applied research (Owen et al., 2012). This is important in view of the argument that in general knowledge production and in particular the innovation process has shifted from mode 1 driven by the scientist in a linear innovation process to mode 2 involving an interactive process of learning with other users and stakeholders (Nowtny, Scott, & Gibbons, 2003). Even in the context of basic research where some elements of mode 1 knowledge production remain dominant, the need to be anticipatory, inclusive and reflexive as well as responsive on other stakeholder remains important.

Table 3 presents examples of some of the most frequently mentioned drivers of RRI.

However, inclusion, participation or engagement should not be exploited as a means of securing specific outcomes, but rather to forge broader societal impact (Pellé, 2016; Sthal, 2014). The purpose of engagement activities is to set things in motion or solidify ongoing development effects; however, the questions of who, why, when to include or even how and to what extent to include seem problematic. One possible alternative could be pre-engagement, which could be a crucial platform to gain intuition about further engagement of the relevant actors in research and innovation (te Kulve & Rip, 2011). As such, pre-engagement could mean mapping of engagement for the research and innovation process, with the aim of achieving responsible outcomes.

4.2. RRI-tools

The RRI-tools domain includes methods or approaches intended for the effective engagement, anticipation and mitigation of potential risks that research and innovation might bear, to ensure that the particular research and innovation is aligned with the norms, values and expectations of society (Som et al., 2010). Table 4 presents some of the most frequently cited themes of RRI-tools.

Knowledge, in this context, plays a crucial role. Innovators, entrepreneurs and societal actors need to acknowledge the fact that individual knowledge would still be limited to address overall socioeconomic, environmental and ethical issues in society.

How to orchestrate and manage knowledge from multiple perspectives is the major topic of the articles under this domain. The themes within the RRI-tools domain are therefore highly concentrated on possible ways of accumulating knowledge and successfully deploying it to overcome societal and environmental challenges. RRI-tools promote the notion of shared responsibility in order to take care of the future (Blok, 2014; Stahl &

Table 4. Major themes on RRI-tools and description.

Thematic area	Theme description
Engagement workshop	Multiple level of analysis and socio-technical scenarios are the complementary approaches for constructive engagement.
Comprehensive and acceptability analysis	The core value judgement in risk analysis is monetary while social acceptance is measured by how much people are willing to pay. This approach actually can be used as reflective and acceptability analysis.
Collective experimentation/social experimentation	Renegotiating between known and unknown. Social experimental nature of emerging technologies.
Anticipation of risk	Anticipating risks and making efforts to prevent is considered as the ultimate responsible attitude.
Technology assessment	A proactive approach, which could provide safe and responsible innovation and avoid controversies.
Foresight	Future studies human-centered science and technology transdisciplinary foresight could be a starting point to elicit public values and societal needs.
	Robustness of credibility of foresight outputs are essential to achieve policy related impact. Important factors in generating the attributed impact: key design choices and processes, the quality and variety of outputs for different stakeholders, the engagement of stakeholders during and after the project, innovative media campaigns. Knowledge of effective mechanisms and foresight impact pathways will help to guide in achieving those impact.
Informed consent	Technologies with great promise could pose ethical issues and these could be avoided considering these issues at the early development of the technology. Informed consent reflects moral responsibility of the innovators, which could resolve ethical issues associated with the implementation of the technology.
Governance by experimentation	
	Experimental approach build on the insight from the approach of strategic niche management and resilience through diversity add the notion of moral learning thus by making it possible to be responsive if the results are socially unacceptable.
Participatory appraisal	Opening up analytic and participatory appraisal in order to consider ignored uncertainties, scrutinize different possibilities and emphasize new options. Participatory appraisal for concrete procedure for the enactment of 'participation' and 'responsibility' in action and not just in empty words.
Collaborative socio-technical integration	Frame work for collaborative integration which is participatory research approach that includes scholarly engagement, ethical, legal and social implication/aspects (ELSI/ELSA) research, laboratory studies, team science, technology assessment, inter- and transdisciplinarity, and public engagement.
Online platform	Online platform for sharing and tracking the activities on emerging technologies.
Online knowledge sharing	Automated learning support system to improve the efficiency and quality of further knowledge flow for sustainable knowledge cooperation among educational institutions and entrepreneurs/innovators.

Coeckelbergh, 2016). This implies transforming the notion of responsibility from liability to care (Owen et al., 2012; Pellé, 2016).

4.3. RRI-outcomes

'Responsible process towards responsible outcomes' is the main aspect of RRI-(Owen et al., 2013). The RRI-outcomes domain thus comprises the themes associated with outcomes as a result of the implementation of RRI-tools in the research and innovation process. Therefore, the themes within this category comprise attitudes, behaviours and impacts of RRI practices in research and innovation activities. For instance, RRI practices can help establish a culture of lifecycle thinking involving critical assessment of environmental sustainability in new product development (Deblonde, 2015; Köhler, 2013; Vincent, 2013). Similarly, responsible attitudes and behaviours would build individual and collective capability to direct research and innovation towards the socioeconomic

Table 5. Major themes on RRI-Outcomes and description.

Thematic area	Description
Life cycle thinking	Modern technologies have led to a substantial increase in resource productivity due to miniaturization of products, however natural resource consumption has not fallen. Even clean technologies use rare earth metals for their efficiency. This led to the question about their sustainability. RRI practices develop life cycle thinking culture among the technology designers and consumers.
Attitude of prudence	Anticipation of the potential environmental, health, security impacts and the ethical, legal and societal impacts of the application of the emerging technology
Responsible attitude	Anticipating risks and making efforts to prevent them. Good intentions always do not ascertain responsible behaviour. Hence, the intentions are to be evaluated from an ethical and political perspective.
Co-creation	Creative ideas are seldom produced in social isolation. Engagement of stakeholders and public in innovation activities could enable in co-creating new knowledge and innovations.
Sustainability impact	Sustainability refers to continuously necessary long-term process. Adaption of responsible approaches in innovation mean sustainability impact.
Social Progress	Innovation focused on the concerns of society as per societal needs, values and expectations mean overall social progress.
Consensus	More transparent debate and inclusiveness in decision-making process among scientific community and society at large creates win-win and acceptable outcomes.

transformation of society (Voegtlin & Scherer, 2015). Table 5 outlines some of the major RRI-outcomes debated in the literature.

4.4. RRI-barriers

The major themes within this category mainly focus on the potential hindrances that RRI practice may face. In the RRI literature, society is viewed as a unit of multiple values comprised of individuals and societal actors such as the state, firms and civil society with conflicting interests (Taddeo, 2016). Directing research and innovation towards 'societal desirability' could be challenging. Consequently, the themes within this domain are the possible obstacles that may arise while implementing RRI aspects in research and innovation policy. For example, RRI promotes open access to research and innovation results (Gupta et al., 2016; Rose, 2012). However, RRI and its successful transition could be challenged as the debate on the relevance of protecting intellectual property rights in research and innovation is an ongoing one (Spinello, 2003). Another example, businesses invest in research and development with the aim of introducing goods and services to the market quickly to gain a competitive advantage over their competitors. For instance, in some multinational corporations, research and innovation are oriented towards outcomes to produce a quick turnover. Researchers, innovators and even managers within such corporations are evaluated as per research and innovation outcomes (Grinbaum, 2013). In such a corporate culture, there is a danger that RRI and its aspiration will be considered as barriers to research and innovation. In the process, it appears that they demonstrate ignorance of ethical and environmental issues, either intentionally or unintentionally (Blok, 2016).

By contrast, societal and environmental activists oppose such practices and force businesses to abandon them (te Kulve & Rip, 2011). Thus, heterogeneous societal norms and values, moral pluralism, power asymmetry, conflicting political ideologies, demands for democratization and governance of research and innovation make RRI, a daunting task (Forsberg, 2014; van Oudheusden, 2014). Nevertheless, bringing all these

Table 6. Major themes on RRI-barriers and description.

Thematic area	Description
Principle-based policy-making	Innovation policy design are guided by principles (either proactionary or precautionary). These principles should not be treated as decision procedures. If done so, values are predetermined, intelligence is gathered, and the results are fed into the principles and ultimately spit out prescription.
Asymmetrical distribution of power	Power distribution among the participants in research, innovation and decision-making could result in status quo hindering the entire process.
Moral pluralism	What is considered morally desirable often stems from conflicting values.
Over inclusiveness	The challenge of navigating between tolerating free riders and stimulating innovations.
Level of perceived responsibility	The perception of individual or shared responsibility might create obstacles in deciding whether to innovate or not.
Conflecting interest	Conflicting interest could mislead the purpose of innovation. This could obstruct in quick and agreed decision.

competing demands and conflicting interests together to achieve 'societal desirability' should remain the aim of RRI (Taddeo, 2016). Table 6 presents the most frequently cited thematic areas of the RRI-barrier domain.

Today's research policies are mainly based on a principle-based decision-making process in the form of rational risk taking or the precautionary principle (Holbrook & Briggle, 2014). The dominant influence of such a principle-based decision-making culture in research policy restricts a responsive attitude by abandoning innovations that might bear further negative consequences for society (Holbrook & Briggle, 2014). Creating harmonious or standardized RRI on a global scale could encounter obstacles due to multiple values, interests and perceptions of what is 'responsible' or 'irresponsible' research and innovation (Arnaldi & Gorgoni, 2015; Ruggiu, 2015).

Inclusion is the main aspect that drives RRI. However, inclusion by itself seems ambiguous. To ensure a smooth transition to the RRI process, appropriate inclusion is essential and defining and determining 'appropriate inclusion' could be a challenge for RRI. Serious consideration of appropriate inclusion must be defined, otherwise there is a danger of over-inclusivity. This could result in the imperil of the integrity of commons (Spinello, 2003), information and power asymmetry (Blok et al., 2015), and unintended consequences of RRI itself.

5. Discussion: application of four RRI domains to regional innovation studies

The descriptive analysis of SLR shows that none of the RRI studies focusing on regional dimensions. The studies on RRI are mainly based on the debate around sensitive technology innovation such as nanotechnology, biotech and digitalization and in and around negative consequences associated with these innovations for the society and the environment. So far, the discussion about RRI has taken limited attention within regional innovation studies. However, the authors argue that RRI debate is highly compatible with regional innovation studies discourse. In facts, RRI studies contribute to debate on regional innovation studies by adding governance dimension, providing guidance on drivers and tools for more responsible regional policies. Regional innovation studies discourse and RRI discourse combined together might provide a synchronized effect on responsible and sustainable outcomes of innovation and entrepreneurial activities for regional development.

The widening grand challenges (Lund Declaration, 2009) and growing disparity at spatial levels resulting in winner and losers (Rodríguez-Pose, 2018; Storper, 2018) are increasingly raising public concerns (Owen et al., 2013) about the unintended consequences of research and innovation. These issues should be addressed proactively on the level of national and regional policies, to ensure that society gains the greatest benefits from science, research and innovation. Therefore, the purpose of innovation should be in and around socioeconomic transformation and overall development of society. RRI address this need by emphasizing the need for a shift in the predominant notion of science and innovation "in" society to science and innovation "for and with" society (Owen et al., 2012).

Engagement of broader stakeholders from the design phase of decision on innovation policy or innovation and entrepreneurial activities becomes the major driver of RRI. However, whether stakeholders are local, national, regional or global, are not specified in RRI studies. Here regional innovation studies might enrich the debate on RRI since stakeholder engagement is an extensively discussed topic within innovation and regional innovation studies. As for instance, innovation is considered and interactive process of learning among different actors (Lundvall, 2010) and recently the implications of networking (Ter Wal, Alexy, Block, & Sandner, 2016), open innovation (Chesbrough, 2006), social innovation (Phillips, Lee, Ghobadian, O'Regan, & James, 2015) and user innovation (Von Hippel, 2005) are ongoing discussion within innovation and regional innovation studies. Regional innovation studies consider engagement as a source of knowledge diversity for innovativeness, co-creation and collaboration for innovativeness (Solheim, 2016). RRI considers stakeholder engagement for co-creation and collaboration to ensure responsible outcomes for societal need based innovation (Guston, 2014; Vincent, 2014). Thus RRI adds value to regional innovation studies by enlightening effects beyond and above economic value realization.

In order to stimulate innovation and development, policy plays a vital role. With growing societal and environmental challenges, it is widely acknowledged that there is a need for policy intervention capable to respond to present and future challenges. Therefore, it is urgent to find effective and efficient innovation and development policy intervention, which should be designed with interaction with broader stakeholder (Barca et al., 2012). However, interaction should not be limited within certain stakeholders or experts and policy-makers. Adapting RRI-drivers in regional innovation and development policies and innovation and entrepreneurial activities would facilitate regional development, which are based on societal needs (Barca et al., 2012).

For responsible and sustainable research and innovation outcomes, it is necessary to know how, what and where to innovate (Bessant, 2013). This requires a diversity of knowledge from broader stakeholders to identify the right innovative idea and anticipate both positive and negative externalities of such innovation and to target it for a sustainable future (Owen et al., 2012). RRI-tools could be instrumental in planning, deciding and executing innovations and innovation policies for regional development. This is mainly because RRI-tools allow in expending anticipatory horizons beyond positive externalities or economic benefit to consider negative externalities and consequences in society and environment.

In general, scholars in the fields of regional innovation studies and economic geography have made substantial contributions to explaining the role of innovation, innovation

networks and innovation policies in regional development in the context of globalization (see, e.g. Asheim, Boschma, & Cooke, 2011; Fløysand & Sjøholt, 2007; Isaksen & Onsager, 2010; Jakobsen & Lorentzen, 2015; McCann, 2008; McCann & Acs, 2011). However, following pressure from spatial competitiveness to catch up with the current trend of globalization, regional innovation policies have mostly focused on the innovativeness of space (local, national and regional) (Asheim, Grillitsch, & Trippl, 2016; Boschma & Frenken, 2011; Boschma, Minondo, & Navarro, 2012; Martin & Sunley, 2011; Trippl, Grillitsch, Isaksen, & Sinozic, 2015) rather than responsible innovation outcomes and innovation impacts. Until recently, both cohesion (Bachtler et al., 2017; Barca et al., 2012) and smart specialization (Foray, 2014; McCann & Ortega-Argilés, 2015) policies has emerged within EU with the purpose of promoting both competitiveness and cohesion in and between EU regions. However, it seems the emphasis, so far is more on competitiveness than cohesion. This raises the question of how new mission-oriented innovation policies can be applied to align these competing goals – achieving competitiveness and economic growth while focusing on the social transformation and environmental sustainability (de Saille & Medvecky, 2016). Therefore, adapting RRI-tools such as foresight could facilitate detailed anticipation of risk and opportunities, alternatives to address present and future societal challenges. Although RRI-tools present different risk assessment approaches, RRI studies have not clearly articulated engagement strategies. However, these are discussed within innovation and regional innovation studies. Action research, social lab and living lab, engaged pluralism are getting attention within regional innovation and regional studies (e.g. Clark, Gertler, Feldman, & Williams, 2003; Fagerberg et al., 2013). RRI can benefit by adapting such engagement strategies to extract necessary knowledge for responsible outcomes. However, within regional innovation studies such engagement strategies are not visibly positioned as a shift towards responsible outcomes.

In light of the above, first, responsible and sustainable innovation outcomes result from collective stewardship where the steering role of government and public policy are crucial (Mazzucato & Semieniuk, 2017). Second, policies should focus on creating and shaping demands that satisfy sustainable societal development (Barca et al., 2012). This can be, for example, cultivated through RRI-tools such as design strategy, opening up, foresight, knowledge sharing among stakeholders in the decision about innovation (Owen et al., 2012). The co-creation of values and shared responsibility are predominant factors that shape responsible innovation policy development (Coeckelbergh, 2016). Such orchestration requires investment by both private and public actors, and a long-term perspective. Furthermore, the eventual significance of policies and strategies for sustainable regional development depend on the effectiveness of the implementation across regions.

Although regions differ in the availability of resources, institutions, knowledge, infrastructure and their needs and capabilities for innovativeness and viable development, the systemic nature of innovation, in particular regional innovation systems (Asheim et al., 2016; Asheim & Gertler, 2005; Morgan, 2007), creates room for responsible development. Further, a recent special issue of European Planning Studies debated this thematic area, focusing on new path development as fostered by policies that incorporate both actor and system-based elements (Isaksen & Jakobsen, 2017). These are certain attempts associated with growing regional challenges. However, desired outcomes of policy interventions, innovation or entrepreneurial activities cannot be ascertained a priori. In light of this, RRI advocates on achieving RRI-outcomes as societal desirable through RRI-drivers and RRI-

tools. As for instance, engaging broader stakeholders can contribute in the diversity of knowledge to focus on need based innovative solutions enhanced by anticipation of risk and opportunities of such innovation in society and environment (Guston, 2014).

Overall, the strategic innovation and development policy, innovation and entrepreneurial activities should follow an iterative, continuous and flexible process of adaptive learning (Stilgoe et al., 2013), which could be advanced by the collective efforts of stakeholders and the public. We believe that the integration of RRI practices within regional innovation policies and practices as well as the adoption of RRI practices in research and innovation activities would make a significant contribution towards sustainable regional development. However, the RRI-barriers point to the challenges of implementing RRI in regional innovation policies. Difficulties in the operationalization of RRI, potential power and information asymmetry among stakeholders, difficulties in obtaining a consensus on 'societal desirability' and resource constraints can lead to the perception of RRI as an obstacle to, rather than a facilitator of, research and innovation (Zwart, Landeweerd, & van Rooij, 2014) consequently affecting regional development. These issues should not be overlooked; rather, the focus should be on overcoming these barriers through reflexive and responsive dialogue, cooperation and collaboration.

6. Conclusion

This paper has endeavoured in understanding the conceptualization of RRI and extent its application to sustainable regional development. In theory, despite its increasing interest, the concept of RRI remains ambiguous. In practice, this makes it difficult to implement, particularly when it comes to regional development. Accordingly, undertaking an SRL, this paper explores the concept of RRI by identifying and categorizing those themes into RRI domains as drivers, tools, outcomes and barriers. It then applies these themes to regional development. Therefore, this study makes a contribution by bringing RRI and regional innovation studies together exploring their effect on one another and combined effect on responsible and sustainable regional development.

Following the ongoing discussions around RRI and regional innovation studies, especially on cohesion and smart specialization, there is an opportunity for engaged pluralism (Clark et al., 2003; Fagerberg et al., 2013) between academic disciplines, innovation studies and regional studies. It seems the conversation about RRI has not gained attention in regional innovation studies and vice versa. Yet, the two discourses are highly compatible and can gain by new insights by shared discussion. For instance, discussion about engagement strategies is present in regional innovation studies as living labs, social labs, action research and community engagement. In fact, there is a way to learn from both discourses and elements from RRI studies can be applied into regional innovation studies and vice versa. Although it is not explicit, a lot of concepts that are used in RRI are also debated in regional innovation studies. This confirms a potential opportunity for both RRI and regional innovation studies to collectively contribute to combined advancement of theory and practice. In the context of regional development, RRI practices could be crucial in planning, deciding and executing innovation policy strategies for a sustainable future. This means adapting RRI into policy formulation and innovation activities could ensure and maintain a balance between cohesion and

competitiveness (Fitjar et al., 2019) resulting in smart, inclusive and sustainable development in and between regions.

This study has implications both for theory, practice and policy. At a theoretical level, our paper contributes by introducing RRI domains as drivers, tools, outcomes and barriers. At the practical level, the findings of this study are crucial for informing policies and practices to align the purpose, process and outcomes of innovation in order to achieve sustainable development. More specifically, focused on the role of RRI-drivers, tools and barriers to achieve responsible outcomes. At the same time, we recommend the inclusion of broader stakeholders and societal actors while deciding and designing innovation policies and critically analysing the consequences of decision through anticipation.

RRI is still an emerging phenomenon; other potential areas for future research could be explored. As for instance, our study revealed that the major driving factor behind RRI is engagement or inclusion. However, as pointed out in our analysis, engagement or inclusion is not a straightforward or easy task. Poorly designed inclusion approaches would result in a situation of 'unresolved decision', which in turn might result in a situation of 'no decision at all' (te Kulve & Rip, 2011). Such a situation would be 'irresponsible' at a time when society is urgently in need of decisions and solutions. Future research should focus on active and productive engagement strategies to design engagement techniques in local, regional, national and global contexts. Whereas regional development strategies have a lot of instruments that entail elements of RRI thinking, the question remains how to change institutions in a way that will provide incentives for all actors involved to follow the ideas of RRI, which is a subject for future research.

Notes

1. The papers in our analysis have used the terms 'Responsible Innovation (RI)' and 'Responsible Research and Innovation' (RRI). This study has considered 'RI' and 'RRI' as the same following a similar approach as Stilgoe and Guston (2017).
2. The literature search was performed in October 2016.
3. The databases used for the literature search cover research across the fields of natural sciences, engineering, management, economics, psychology, health, epidemiology and medicine.
4. *The Journal of Responsible Innovation* was not indexed in major databases at the time of our literature search.
5. The list of selected papers will be made available on Research Gate.
6. References presented here exclude 126 articles that are subject of the analysis. (The full list of 126 articles with references available at Research Gate link to be provided.)

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Appendices

Appendix 1: Sample reading guide

SLR reading guide	
1. Article title	Informed consent in asymmetrical relationships: an investigation into relational factors that influence room for reflection
2. Author(s)	Shannon Lydia Spruit, Ibo van de Poel and Neelke Doorn
3. Year of publication	2016
4. Journal	*Nanoethics*
5. Research question	How can informed consent be applied in a nanomaterial context?
6. Key concepts	Informed consent, nanomaterial risks, relational autonomy, room for reflection, interpersonal relationships, dependency, personal proximity, shared interests
7. Main area	Ethics
8. Key findings	This paper discusses three features that make valid informed consent obtainable – dependency, personal proximity and the existence of shared interests. It discusses informed consent in a new setting. Normally, informed consent is used between patients and doctors, or between researchers and research participants. Informed consent allows individuals to make their own decisions concerning their exposure to potential dangers, emphasizing the importance of individual autonomy and responsibility for balancing risks and benefits. However, consent cannot be informed if it has no solid knowledge base, which is the case for nanotechnologies. The paper looks at situations where informed consent could potentially be obtained – between producers and consumers, or between employers and employees in the case of engineered nanomaterials
8a. Practical implications /tools	Not clearly specified but, generally speaking, informed consent might lead to the anticipation of risks and more responsible decision-making
8b. Theoretical implications	In some senses, this article discusses anticipation of risk and, in that way, enhances responsible innovation in nanotechnologies. It develops a relational approach to informed consent

Appendix 2: List of 126 conceptual papers divided by journals

Name of journals	Number of papers
Medical health Care and Philosophy	2
Technology in Society	5
Science Engineering and Ethics	11
Philosophy of Management	2
Technology Forecasting and Social Change	4
Journal of Information, Communication and Ethics in Society	4
Economy and Society	1
Research Ethics	1
International Journal of Perfomability Engineering	1
Clinical Ethics	1
Nanoethics	15
Europena Journal of Future Research	2
Journal of Agricultural and Environmental Ethics	2
Journal of Acedamic Ethics	2
Agriculture and Human Values	1
Procedia Computer Science	2
Seminars in Ultrasound CT and MRI	1
Theoretical Foundations of Chemical Engineering	1
Transnational Environmental Law	1
Journal of Knowledge Economy	2
Journal of Technology Transfer	1
Life Sciences, Society and Policy	5
Journal on Chain and Network Science	2
Annals of Physical and Rehabilitation Medicine	1
Science and Public Pology	2
Futures	5
Ethics and Information Technology	1
Information and Management	1
Minds and Machines	1
Innovation-The European Journal of Social Science Research	1
Foresight	1
Diagnostic Histopathology	1
Public Understanding of Science	1
Biological Theory	1
Ethics and Politics	2
Seminars in Pediatric Surgery	1
Journal of Business Ethics	1
Synthetic and Systems Biotechnology	2
Journal of Open Innovation: Technology, Market and Complexity	1
Social Studies of Science	1
Biotechnology Journal	1
Journal of Nanoparticle Research	1
BioSocieties	2
Neuron	1
Journal of Cleaner Production	1
Applied Ergonomics	1
Toxicology	1
Robotics and Autonomous Systems	1
Minerva	2
Current Opinion in Environmental Sustainability	1
Surgical Endoscopy	1
Science & Education	1
Journal of Environmental Radioactivity	1
Environmental Science & Policy	1
Journal of Science Communivation	1
Environmental Science and Technology	1
Journal of Responsible Innovation	15
Total	126

Paper II

Governing digital innovations for responsible outcomes – the case of digital healthcare and welfare services

Raj Kumar Thapa & Tatiana Iakovleva

Abstract

Digital innovations integrated with Responsible innovation (RI) offer great potential to address complex societal challenges in the healthcare and welfare sector but depend on how well firms can manage the innovation process to ensure socially desirable solutions. However, there is a lack of empirical studies examining whether RI principles can be integrated into a firm's innovation development process. This paper aims to fill this gap through longitudinal case studies of six digital start-ups in the healthcare and welfare sector from 2016 to 2019. We followed innovation development in these firms, observing the stakeholder inclusion, pivotal moments and the emergence of new solutions based on the need-solution interactions. We found that stakeholder inclusion is critical. Therefore, we suggest that managers and entrepreneurs consider including a diversity of stakeholders and users from the design phase throughout the innovation process.

Keywords: Responsible innovation, user engagement, stakeholders, inclusion, digital innovation, healthcare and welfare sector, innovation process, innovation governance

1. Introduction

Digitalisation is transforming all sectors of our life. It has emerged as a potential solution to healthcare and welfare service provision crises (Bessant et al., 2017). It could add potential benefits to users by increasing the ease of access to products and services while driving down the costs of provision (Christensen, et al., 2017; Yoo et al., 2012) and could bring several innovation choices and entrepreneurial opportunities (Nambisan, 2017; von Briel et al., 2018). Therefore, digital innovation is getting attention from the world of policy-making, governments, businesses, and the public (Greenstein et al., 2013; Huang et al., 2017).

However, like other novel technology innovations, digital innovations often lead to users' and stakeholders' concerns about privacy, safety, and security (Hinings et al., 2018; Marques & Ferreira, 2020; Stahl et al., 2016). This is especially true in the healthcare and welfare sector, which involves multiple stakeholder interests, including patients, users, healthcare professionals, insurance companies, the government and the public sector (Kerr & Glantz, 2020). Therefore, the traditional linear problem-solving approach when innovations developed in R&D institutions reach the market does not always adequately address challenges in the healthcare and welfare sector (Vakili & McGahan, 2016). In addition, innovative solutions developed without deliberate stakeholder inclusion are at risk of rejection by the market (Ben-Menahem et al., 2016; Kurup et al., 2011). Governing innovations such that they can be channelled to address healthcare and welfare service challenges have become imperative (European Commission, 2016; Official Norwegian Reports, 2011; The Norwegian Directorate of eHealth, 2020).

Accordingly, responsible innovation (RI) has emerged as an approach to the governance of the innovation process (European Commission, 2011; Owen & Pansera, 2019; von Schomberg, 2011). It emphasises a broader stakeholder inclusion, anticipation of intended and unintended consequences of innovation, reflection on the purpose of innovation and responsive to the needs, concerns and expectations of stakeholders and the public from the beginning throughout the innovation process (Owen et al., 2013 a; Stilgoe et al., 2013). It seeks to facilitate firms in developing desirable and acceptable innovations (Stahl et al., 2017; Stilgoe et al., 2013). The deliberate inclusion early in the innovation process enables firms to analyse the root cause of societal problems and need-solution interactions to assess the innovations in question (Owen et al., 2013 a; Von Schomberg, 2019). Moreover, inclusion allows a platform for detailed anticipation of the impact of innovation on society (Foley et al., 2018; Guston, 2014),

enabling collaboration and the co-creation of solutions to societal challenges (Marschalek et al., 2022; Timmermans et al., 2020).

However, despite the potential benefits of inclusion in the innovation process (Long et al., 2020) and healthcare innovation (Batayeh et al., 2018; Lehoux et al., 2018), the operationalisability of RI at a firm level remains ambiguous (Oftedal et al., 2019 a; Stahl et al., 2017). As such, firms and entrepreneurs lack explicit moral decision-making criteria in the innovation process to address diverse stakeholders' concerns (Bennink, 2020; Crockett et al., 2014). This study aims at exploring the inclusion of stakeholders and users by firms to understand when (at what stage of the innovation process), how (the degree of stakeholder engagement) and whom (diversity of stakeholders) they include in the innovation process. We also seek to explore the outcomes of such engagement, challenges and opportunities the firms and entrepreneurs experience during the inclusion of stakeholders in the innovation process.

Therefore, looking at the innovation process in the digital healthcare and welfare sector, we seek to answer the following research question: ***How does the inclusion of a diversity of stakeholders affect the governance of the innovation process in firms?***

This work aims to answer the research question through longitudinal case studies of six digital start-ups in the healthcare and welfare sector in the Western region of Norway during 2016–2019. The firms are members of the Norwegian Smart Care Cluster (NSCC), established in 2013. It comprises 250 private and public actors involved in promoting the digitalisation of healthcare and the welfare sector. We followed innovation development in these firms, focusing on inclusion and its impact.

The paper demonstrates that the inclusion in the innovation process allows for continuous loops of need–solution interactions enabling innovations to launch earlier to the market. However, deliberate inclusion requires additional time and resources, which start-up firms often lack. Therefore, we suggest intermediate organisations, like clusters, living labs, incubators, and accelerators, can play a significant role. This also requires that policies are in place to stimulate firms and intermediate for collaboration and deliberate stakeholder inclusion throughout the innovation process.

The paper's remaining sections are structured as follows: in section 2, we present the theoretical background, followed by the research design and methods in section 3. Section 4 presents the findings, followed by a discussion in section 5 and a conclusion in section 6.

2. **Innovation and problem solving**

Innovation is imperative to societal problem-solving (Fagerberg et al., 2013; Martin, 2016). However, how practical innovations are for society often depends on the complexity of the problems (Leiblein & Macher, 2009) and the governance mechanism (Felin & Zenger, 2014). Traditionally, the underlying assumption of the problem-solving innovation approach is that the problem has been well-defined (Ben-Menahem et al., 2016; Volkema, 1983). This model assumes that the innovation development process proceeds smoothly through design and testing into the market launch stages. This model is instrumental when problems are fixed at the beginning of the solving process and remain unchanged. However, in many situations, the initial problem specification must be constantly reformulated (Kurup et al., 2011; Thomke & Fujimoto, 2000), making this linear innovation approach challenging to apply in innovating the right solutions (von Hippel & von Krogh, 2015). This explains the accelerating interest in 'agile' approaches to innovation in which there is regular cycling between problem and potential solution and 'pivoting' towards an optimum that meets the concerns of users and multiple stakeholders.

Innovation is a dynamic interactive process; no firm can innovate in isolation (Tidd & Bessant, 2020). They interact with stakeholders for the specialised knowledge and expertise necessary for innovation (Fagerberg et al., 2005). They search and network with external resources (Chesbrough, 2006). However, they emphasise the economics of searching (Laursen & Salter, 2006) and might ignore alternative solutions if they require more time and resources to develop. This issue can result in solutions that bear negative externalities. For example, designing digital tools to monitor the behaviour of older people in smart houses might lead to various privacy issues, or using artificial intelligence to diagnose diseases could create a dangerous situation where decisions are left to machines and algorithms rather than human beings (Iakovleva et al.). To avoid such negative consequences, innovators should explore various solutions and choose the best alternative path for consideration (Pich et al., 2002).

Further, sometimes firms innovate solutions which can be technically efficient but may not necessarily meet users' and stakeholders', needs and expectations (Bessant et al., 2017). Hence, broader problem and solution landscapes should be explored with users and stakeholders (von Hippel & von Krogh, 2015). The need-solution interaction enables a solution landscape of a pool of need-related information. It allows to keep the design space of the innovation process open as long as possible and to pivot and adapt towards the changing stakeholders' and users' needs (Bessant et al., 2019).

Firms need to strategically orient innovation activities to ensure optimal desirable solutions that can address societal challenges (Bessant, 2013; George et al., 2016; Von Schomberg & Hankins, 2019). They must include a diversity of perceptions, opinions, and interests (Oftedal et al., 2019 b). Opening up innovation activities to inclusion allows firms to remain innovative and competitive (van de Poel et al., 2020). However, governing the innovation process efficiently to enable such inclusion in the firms' innovation process need further exploration. RI approach in innovation has emerged as an ambitious approach.

Accordingly, the following section looks at the role of RI in facilitating need-solution interactions among firms and stakeholders and govern firms' innovation process towards problem solving solutions.

Responsible innovation (RI) approach

Responsible innovation (RI) has emerged as an innovation governance approach to ensure innovation incorporates stakeholders' societal and ethical concerns (Stilgoe et al., 2013; von Schomberg, 2013). Scholars argued that RI could help steer innovation towards broader societal impact (Long et al., 2020; Owen et al., 2013 b; Schuijff & Dijkstra, 2020). Harnessing the potential of technological innovation to benefit industry and society, policymakers and industrial actors need to consider stakeholders' and users' concerns about innovations. The question of responsibility in technological innovation has long been debated. For more than five decades the researchers have argued for some degree of technology assessment and control, trying to understand how innovators anticipate and explore the likely consequences of technological innovation decisions (Guston, 2014; Schot & Rip, 1997; Stilgoe et al., 2013). They argue that the current ethics-reviewing procedures within technology innovation failed to address broader concerns, such as the potential consequences of innovation (Jirotka et al., 2017).

Stilgoe et al. (2013) define RI as stewardship of science and innovation in the present to take care of the future (p. 1517). For this to happen, the societal actors and innovators should interact and become mutually responsible with a view to ethical acceptability, sustainability, and the social desirability of the innovation and its outcomes (von Schomberg, 2011, p. 9). Further, RI can be viewed as a tool for extracting and exploiting the best knowledge for innovation purposes and for shaping innovation towards desirable innovation outcomes that are socially, economically, and environmentally robust (Owenet al., 2013b).

Stilgoe et al. (2013) proposed four RI dimensions: inclusion, anticipation, reflexivity, and responsiveness. Inclusion enables firms to decide on whose needs, voices, and interests should be considered and at what stage of the innovation process. Anticipation encourages firms to reflect on intended and unintended outcomes and their societal impact. Reflexivity enhances the reflection of the underlying motivations, goals, worldviews, and assumptions driving the innovation. Finally, responsiveness addresses how to respond to the stakeholders' and users' concerns about innovations (Stilgoe et al., 2013). The rationale is that the inclusion of a diversity of stakeholders and users allows firms to become acquainted with the needs and expectations, anticipate the opportunities and challenges as well as the consequences of the solutions, reflect on the feasibility and efficacy of the solutions and respond to the stakeholders and users' concerns, opinion, and feedback about the potential solutions (Stahl et al., 2017; Stilgoe et al., 2013; von Schomberg, 2013).

However, achieving RI goals depends on how firms integrate RI into innovation activities since they are the primary driver of innovation. RI discussions are often at the policy level (Loureiro & Conceição, 2019; Schuijff & Dijkstra, 2020) and are limited to research projects, specifically those funded by public funding bodies (Bernstein et al., 2022; Novitzky et al., 2020; Thapa et al. 2019). Far less is known about enabling it within an operating context like a firm (Blok & Lemmens, 2015; Lubberink et al., 2019; Stahl et al., 2017). Despite growing studies on RI in industry, ambiguity on its implementation in innovation activities at the firm level still exists (Lubberink et al., 2017; Stahl et al., 2017). Dreyer et al. (2017) suggested that RI must find ways to integrate into existing industry practices instead of reinventing the wheels. They meant that there should be simple, clear, and credible guidelines for implementing RI in the innovation process (Dreyer et al., 2017). Further, to practice RI, firms need to see the benefits of practising RI (van de Poel et al., 2020).

Although all four dimensions are vital, we specifically look at the inclusion dimension of RI. We aim to explore the inclusion of stakeholders by firms to understand the underlying motivation of inclusion, the process by which they are engaged, at what stage of the innovation process engagement happens and the resulting outcomes from inclusion. We define *inclusion* as involving different stakeholders and users in innovation activities to represent their ideas, creativity, and voices and facilitate dialogue and discussion that provide social intelligence (Stirling, 2005; Von Schomberg, 2019). Furthermore, deliberate inclusion helps the development of perceived ownership of the innovation outcomes and motivates creativity (Felin & Zenger, 2014; Timmermans et al., 2020). Moreover, including the public and all the relevant

actors in the governance of science and innovation is a growing requirement for legitimacy (Timmermans et al., 2020). There is an increasing belief that meaningful stakeholders and user inclusion can enhance shared decision-making, a vital component for increasing innovation impact on problem-solving. Thus, it is critical to reflect on what *type of stakeholders* to include, the *mode of participation*, when to *include* them, and *how to include* them (Silva et al., 2019).

Type of stakeholders

Stakeholders are individuals or groups that can affect or be affected by the fulfilment of the organisational goals (Freeman, 2010). The most typical stakeholder that firms tend to include is economic stakeholder, including employees, suppliers and potential customers (Blok et al., 2015). While innovation management literature emphasizes user and customer inclusion, RI advocates for the broader inclusion of economic and non-economic stakeholders from industry, civil society, and research, including the public, in the innovation process (von Schomberg, 2013). Several non-economic stakeholders, such as governments, competitors, consumer advocates, environmentalists, special interest groups, and the media, play a fundamental role in the credibility and acceptance of business activities (Ayuso et al., 2006).

Mode of participation

Goodman & Sanders Thompson (2017) classified stakeholder engagement into three broad categories: non-participation, symbolic, and engaged participation. Non-participation is characterised by a one-way interaction where the voice of users and stakeholder groups with little or no influence over the decision-making process needs to be improved (Arnstein, 1969; te Kulve & Rip, 2011; Vincent, 2014). In symbolic participation, stakeholders and users participate in discussions, and they have a voice. Even so, it is not guaranteed that their voices will be heard and that there will be a change in the status quo. Engaged participation, however, allows stakeholders with traditionally limited power to share decision-making authority with influential stakeholders (Goodman & Sanders Thompson, 2017; Reed, 2008). Engaged participation is the essence of inclusion in RI.

When to include

It is strategically vital for firms to decide at what stage of the innovation process should include users and stakeholders. Innovation process theories typically describe a “development funnel” of innovation as a sequential process consisting of several stages, including outlined concept,

detailed design, testing, and launch phases. While there are several challenges in engaging multiple stakeholders and users in each stage of the innovation process, engaging them from the ideation phase onward is significant (Bessant et al., 2017). Engaging stakeholders and users early provides firms with opportunities for experiential learning, familiarising their needs, concerns and expectations, collaboration and co-creation (Flipse & van de Loo, 2018; Timmermans et al., 2020). Moreover, inclusion at the ideation or design phase of the innovation process allows firms to assess stakeholders' and users' needs early on (von Hippel & von Krogh, 2015) and early pivoting in response to the interactions (von Hippel & von Krogh, 2015; Wilson & Doz, 2011). Such initiation could reduce launch time and build trust among users and stakeholders, which is essential for scaling innovation for societal problem-solving and organisational growth (Scholten & Van Der Duin, 2015; Sunday & Vera, 2018).

How to include

Several stakeholder engagement techniques are practised in innovation management and RI approaches depending on the purpose of stakeholder engagement. Traditionally stakeholder interaction techniques like interviews, collaborative dialogue sessions, and focus groups (De Jong et al., 2016; Demers-Payette et al., 2016) are practised in innovation. Further, approaches like workshops and discussions with groups of experts (Bremer et al., 2015; De Jong et al., 2016; Decker et al., 2017; Demers-Payette et al., 2016) are also familiar in research and innovation projects. Open innovation (Chesbrough, 2006) is becoming vital in innovation management. Moreover, online platforms (van Oost et al., 2016), online knowledge sharing (van Oost et al., 2016)., design thinking (Brown & Katz, 2011), and walkshop approach (Wickson et al., 2015) have emerged as practical approaches for stakeholder and public engagement in research and innovation activities. Nevertheless, the social labs (Hassan, 2014) approach is emerging as an experiential learning platform for need-solution interactions to find optimal desirable solutions for grand societal challenges (Marschalek et al., 2022; Timmermans et al., 2020).

While innovation management literature emphasises engaging with stakeholders and users, they are limited mainly to consultation. RI, however, advocates the significance of stakeholders and user inclusion early in the innovation process for meaningful collaboration for desirable, sustainable, and responsible innovation outcomes that can address grand societal challenges.

3. Research design

3.1 Design and method

A multiple case study research design was used to collect data longitudinally from six start-up firms—A, B, C, D, E, and F, chosen among the 190 firms operating in digital healthcare and welfare services and are members of the (NSCC). We followed a homogenous sampling strategy while selecting the cases (Patton, 2002). Therefore, we adopted the following selection criteria: (1) Either start-up firms or innovation projects within small or medium-sized firms in their early stage of development. (2) All the firms focus on digital innovation in the healthcare and welfare service sector. This approach allowed for some variations in the innovation process and comparisons among start-up firms. After consultation, the head of NSCC provided a list of around 20 firms that suits our selection criteria. Only nine firms agreed to collaborate with this research project. We considered only six firms for analysis since the others were established firms starting digital innovation as their separate business unit. Those firms have a different network and resources regarding stakeholder engagement than the rest of the sample.

Primary data collection involved semi-structured interviews in autumn 2016/spring 2017 and follow-up interviews in 2018 and 2019 with 27 informants: 12 founders or chief executive officers (CEO) of the firms and 15 stakeholders associated with e-health innovation. Each interview lasted 60-80 minutes during the first round and 40-60 minutes in the second round. We believe a founder or CEO can reflect a firm's situation and vision. The stakeholders included municipalities, investors, users, healthcare educators and care providers. Secondary sources included the firm's website, documents, and information collected at conferences and workshops on digitalising healthcare and welfare services. Table 1 below presents the value proposition, target market and solution developed by each firm.

Table 1: Case firm's description.

Firms	Value proposition	Target Market	Solution
A	Competence-building via courses, interaction and training among healthcare professionals	Municipalities, private nursing homes and care centres.	Realised in an app and could be assessed in computers, smartphones or similar devices.
B	Motivating the public for healthy living through outdoor and social events as well as empowering them to take care of their personal experience data.	Municipalities Private businesses	Realised in the form of the app (the firm is also in the process of developing customised hardware in the form of a wristband)
C	Effective management of resources among the volunteer organisations, including healthcare sectors, in order to provide services in a meaningful way.	Volunteer organisations, event organisers and politicians	Realised in the form of an app
D	Empowering users to assess their own health status due to lifestyle changes and enabling them to monitor their health condition for healthy living.	Municipalities, schools and colleges	Realised in software
E	Facilitating two-way communication between the user and reference person in case of emergency.	Private market	Realised in a combination of digital hardware and software
F	Providing the possibility for elderly people secure living independently in their own homes.	Municipalities entering the private market	Realised in a combination of digital hardware and software

3.2 Data analysis

We began data analysis by accumulating all the data gathered through transcripts from interviews, documents, observational notes, information available on websites and notes prepared while attending events. We read the entire data set to gather an overall picture of the phenomenon studied. We adopted a qualitative content analysis approach (Elo & Kyngäs, 2008). To focus on the trustworthiness of the study's findings, we followed an approach to scrutinise the trustworthiness of every data analysis phase, including the data preparation, organisation and reporting of results (Elo et al., 2014). We focused our analysis on the stakeholder engagement strategies of the firms: with whom they engage, the mode of participation, when it happened in the innovation process, the outcomes of engagement, and opportunities and challenges of engagement in the innovation process.

4. Findings

We summarise the findings of the analysis in figure 1 below. The figure reflects stakeholder engagement categories that the firms practise in the innovation process and the outcomes from such engagement activities.

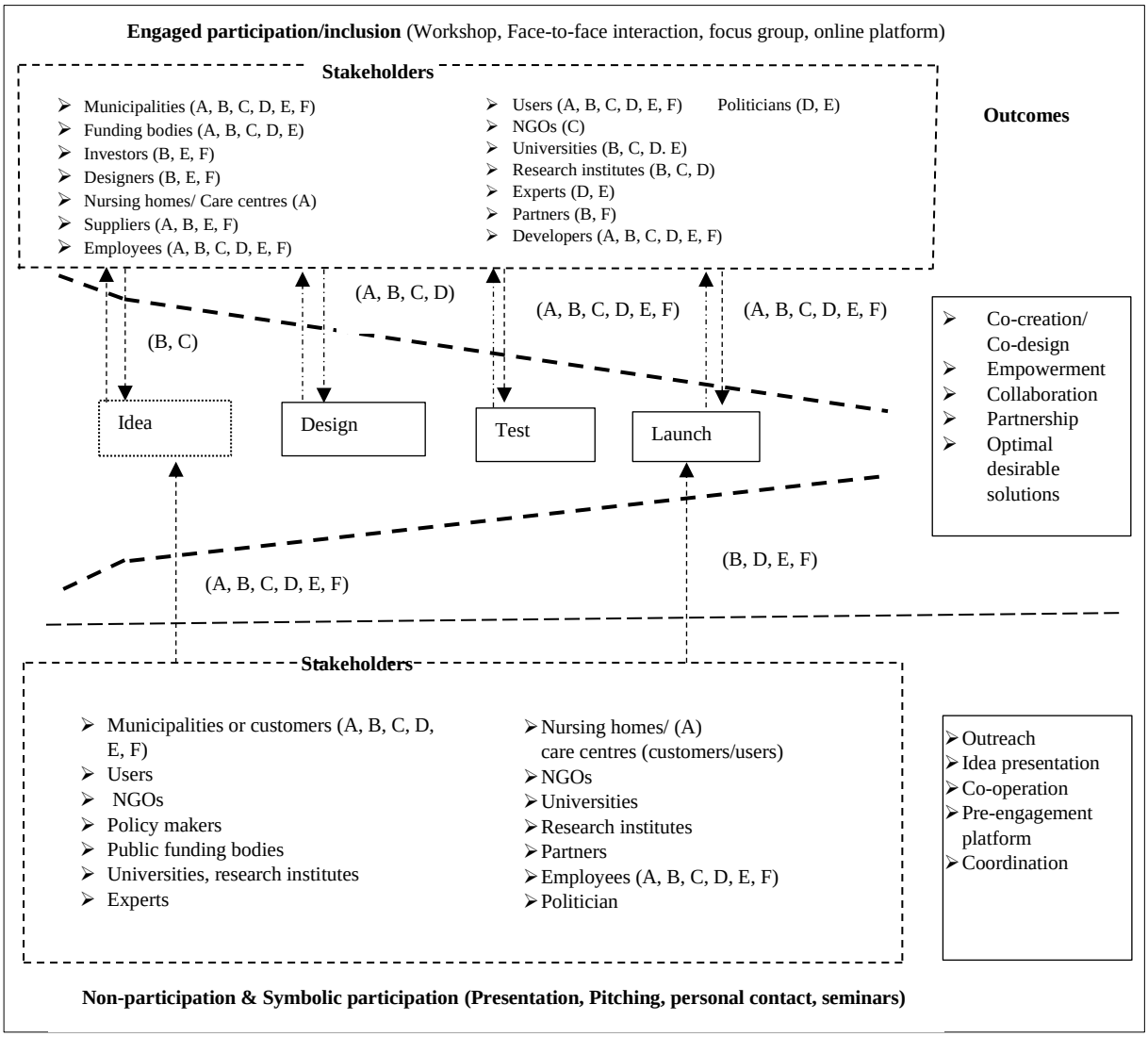

Figure 1: Stakeholder engagement in the innovation process of firms

We unpack the above figure to elaborate on findings on stakeholder engagement in firms' innovation process. Firms interact with a diversity of stakeholders, both economic and non-economic. The economic stakeholders ranged from employees, investors, the municipalities (major customers), nursing homes and care centres, suppliers, software developers and partners. Non-economic stakeholders were users, NGOs, volunteers, public funding bodies, students, older citizens, healthcare providers, healthcare experts, local politicians, universities, research institutes and the public. Analysis revealed that all the case firms practised non-participation,

symbolic participation and engaged participation in innovation. Stakeholder participation differed among firms based on the types of stakeholders they engaged with and the stages in the innovation process in which they engaged. Moreover, the analysis revealed some of the firms' obstacles during stakeholder engagement.

Stakeholder engagement in the innovation process

Nonparticipation and symbolic participation

All three categories of stakeholder engagement are identified across all the case firms (A-F). They performed nonparticipation or symbolic participation at the ideation phase of the innovation process, mainly to reach out to the stakeholders and users with their innovative solution ideas. Such interactions aimed to seek funds, knowledge, and resources essential for developing ideas into innovative solutions. However, some firms used such interactions to seek a partnership or financial and expertise support throughout their innovation journey. Moreover, they got collaboration opportunities. In some cases, nonparticipation and symbolic participation allowed firms to be acquainted with the economic and noneconomic stakeholders and engage in the innovation process. In some cases, however, firms performed nonparticipation and symbolic participation at the market launch phase to sell the product/ services to the customers.

In a seminar organised by the NSCC, two entrepreneurs of firm A presented their idea to the actors from municipalities, nursing homes, care centres, universities, knowledge brokers, representatives from Innovation Norway and healthcare workers. The firm managed to get seed funding from Innovation Norway. Six nursing homes and care centres in the Stavanger region were willing to collaborate with the firm.

Similarly, firms B, C, D, E, and F pitched or presented their solution ideas to investors, public funding bodies, customers, and potential users. With this initial stakeholder engagement, firm B, besides support from the municipalities (primary customers), got access to potential userbases- the Norwegian climbing and hiking association members. Firm C was able to gain seed funding and access to customers and potential users of their digital platform. Firm E got a green signal from the municipalities that they would consider buying their products once tested.

In some cases, however, firms performed nonparticipation or symbolic participation to reach out to the customers at the launching stage to sell their products or services. For instance, firm F could sell digital security alarms to the municipalities (a major customer) since the product met customers' urgent needs and specifications. The solutions were technically

efficient and could address problems, including service providers. However, the users (older citizens) denied adopting and using the solutions since they did not meet their expectations and concerns, specifically regarding the device's design. The firm was forced to rethink the design of the solutions. In the case of firm D, however, the firm used a symbolic participation engagement approach with the municipalities, primary customers. The firm coordinated with the municipalities, launched the online self-health assessment platform among the municipal employees, and chose a nonparticipation engagement approach to educate the employees to use the platform. The employees participated in the programme but did not prefer the digital platform; instead continued with the traditional paper version. In this case, the firm could not include users' needs and expectations.

Analysis showed that nonparticipation and symbolic participation could help reach out to larger groups of stakeholders to share innovative ideas and seek financial and other resources necessary for developing innovative solutions. Firms can find networking opportunities if the participants see value in innovative ideas. Such engagement approaches can be beneficial if the firms adopt them in the ideation phase of the innovation process. However, the firms should ensure a broader stakeholder group, including potential solutions users. Practising such engagement approaches at the launch stage of the innovation process may ensure winning customers, but not necessarily the end-users and other stakeholders. Our findings suggest that nonparticipation and symbolic participation approaches are limited primarily to one-way communication. Such engagement approaches can act as a stimulation for engaged participation. However, the engagement should be broader than the economic stakeholders and influential actors.

Engaged participation/inclusion

The findings showed that all the firms in this study practice inclusion in the innovation process. However, there are differences across the cases concerning the type of stakeholders included and the phase in the innovation processes they were included. Firms typically included users and potential users through face-to-face interaction, focus groups, or testbeds approaches.

In some cases, they included noneconomic stakeholders, specifically the users from the ideation phase of the innovation process onwards, like in the case of firms B and C. In some cases, however, inclusion happened only in the innovation process's test and launch phases, as seen in E and F cases. Moreover, the findings suggest that the early inclusion of users and other stakeholders in the innovation process enabled firms to interact with their needs, values,

expectations, and concerns. The participants who saw the value of the potential solution showed their interest in collaborating with the firms in other phases of the innovation process. In such situations, the firms got the opportunity of experiential learning and co-designed and co-created solutions with the engaged participants.

Inclusion in the innovation process enabled firms to undergo changes and modifications of service design and specifications based on consumer needs making them more desirable. For example, firm D initially failed to execute the digital self-health assessment tool for the municipal employees and got the idea of developing solutions for school students instead. The firm organised a workshop early in the design phase of the innovation process for engaged participation. The workshop participants were school administrators, students, school nurses, teachers, software developers, health experts, and representatives from municipalities, incubators, and public funding bodies. Including diverse stakeholders and users in the workshop enabled early need-solution interaction among the participants. Thus, the firm designed and developed a digital self-health assessment platform with the potential users (students and school staff) based on their needs and expectations, tested and successfully executed the solutions. From the stakeholders' and users' interactions, the firm gained ideas and insights about service design and user interphase through their constructive feedback. The CEO of the firm shared his experience with inclusion during the innovation process:

"We conduct workshops with students, teachers, and nurses to see the effectiveness of our service, and we make changes all the time based on the feedback in the workshop. The students are smart; they know certain things we have never considered. It is interesting and a learning process for us as well."

As the above example demonstrate, engaging diverse groups of participants early in the innovation process increased the likelihood of adopting and scaling the products and services. The data analysis also revealed that collaboration with diverse stakeholders in the innovation ecosystem and the users created a ripple effect, enabling them to scale up the solutions and organizational growth.

Keeping diverse stakeholders engaged throughout the innovation process was challenging for the firm. However, those who committed to engaged participation turned out to be the ambassador of the solutions, and the firm could distribute solutions to other customers and consumers through a ripple effect.

The CEO of firm D expressed his experience with engaged stakeholders in the innovation process:

"Bringing together the teachers, nurses, administration, and municipalities assisted in commercialising our solution because you work together with them and identify their actual needs and concerns. Designing and testing the solution together enabled them to understand the concept to make them responsible, a good way of manipulating, thinking and realising the value of our solutions. They will also recommend to others that they should buy or continue with the solution for themselves".

The firm was able to execute its solutions for several other schools from other municipalities in the country. The firm is now in dialogue with the universities to launch the service to students and employees.

Firm E innovated digital technology to monitor heart failure. The firm performed engaged participation with municipalities, health experts, health educators, and university and IT experts in designing and developing a prototype. However, the firm should have noticed end-users' inclusion in the design phase of the innovation process. With the coordination with the municipalities (primary customers), the firm engaged with patients in nursing homes in the test phase of the innovation process. The firm changed and adjusted the feature and design of the product several times based on the stakeholders' feedback and brought in the potential users of the technology only during the test phase of the innovation process. However, most potential users engaged in the testing phase showed scepticism about adopting and using the product. Although the product was technically efficient and could meet users' needs but did not meet their value and expectations. The engaged user groups provided the idea of redesigning the product with a smartwatch instead of simply an armband which could address their concerns. The firm needed to redesign the device, which incurred additional investments and time and delayed the commercialisation of the product. The entrepreneur shared his experience while testing the solution with the potential users:

"*We have also added a new… a few new features, but I think maybe the main thing has been the design adjustments. Making it look like a watch, not like a big, large grey thing with a red button on. The problem for most of them was that they don't want to… they don't want other people to know that they have an issue that needs taking care of".*

Firm F engaged mainly with the economic stakeholders, municipalities and suppliers in the innovation process and developed digital security alarms for older citizens in nursing homes

and care centres with the specification and needs of the customers. They engaged with care providers and older citizens mainly at the test and launch phases of the innovation process. When the product was introduced to older citizens, they denied using it. The older citizens felt uncomfortable with the design of the device. In this case, the firm could also meet the customers' needs but failed to meet the users' needs since the firm was unaware of what the users value and expect.

"We delivered to the municipalities, and they implement the services and products. We believe that they work with the end users, so we are not working with them". Respondent firm F

The firm needed to redesign and make the solution user-friendly based on users' feedback, which caused additional costs and delays in commercialisation.

Challenges of stakeholder inclusion in the innovation process

We identified multiple stakeholders in the healthcare and welfare sectors. The customers are mainly the municipalities or public bodies; users range from healthcare service providers, patients, NGOs, volunteers, students, employees, older citizens, and the public. Other stakeholders in the innovation ecosystem are partners, policymakers and politicians, health experts, IT experts, designers, incubators, knowledge brokers, care clusters, public funding bodies, research institutes and universities. The noneconomic stakeholders external to the innovation in question play a vital role in innovation acceptance and diffusion.

Our findings suggest that inclusion in the innovation process is getting acknowledged by the business communities. The advantage of including diverse stakeholders in innovation is getting recognised among firms and entrepreneurs. Despite these, they expressed several challenges to inclusion in the innovation process. The major challenges are listed below:

Difficulties in reaching out to influential stakeholders for engagement

The findings showed that the case firms face several challenges in reaching out to "gatekeepers" or influential stakeholder groups. If they somehow managed to reach out to them, it was hard to engage them in the innovation process. For instance, municipalities are essential to innovation in Norway's healthcare and welfare service. However, different departments and administration layers are responsible for decision-making. The firms expressed their difficulties and frustrations in identifying the correct authoritative figure while seeking inclusion in the innovation process. The CEO of firm D expressed his challenges:

"The municipalities say they should work with welfare technologies, but they have no idea how it should be. When businesses call them, there is a wall! There is a huge challenge to engage them. There was a report from a research institute about how difficult it was to connect the companies with the municipalities because it takes so long, the companies like us are dying" CEO firm D.

Firms need help to map stakeholder groups and bring them together with the other stakeholders and users in the innovation process.

Time and resource constraints

Although the inclusion of a diversity of stakeholders, both economic and non-economic, in the innovation process proved beneficial, firms, especially start-ups, find it challenging due to time and limited resources to organise engagement activities throughout all the phases of the innovation process. The firms meant that contacting stakeholders and potential users and finding suitable dates and venues for all the participants took extended time. Moreover, the cost associated with hosting such engagement activities in the innovation process is costly. Firms and entrepreneurs expressed that they cannot allocate additional investments and time for administrative work with their limited resources.

Findings revealed that engaging influential stakeholders were challenging because they could hardly allocate time. Firms needed to reschedule or even cancel the engagement workshop several times.

Challenges of including vulnerable user groups in the innovation process

Even though the firms demonstrate their motivation for inclusion and its advantages, they face several challenges while practising inclusion. They think including user groups such as patients, especially the vulnerable patients with dementia, was critical since they needed ethical approval and permission from authorities in hospitals, care centres and nursing homes. Therefore, in some cases, the firms are forced to limit their inclusion to municipalities which provide healthcare and welfare services to citizens and are primary customers of the firms.

Power and information asymmetry

To facilitate inclusion, the Norwegian Smart Care Cluster (NSCC) initiated an open platform for the engaged participation of actors in the innovation ecosystem. However, the young firms, especially the early start-ups, seemed sceptical about adopting open innovation approach due to information asymmetry. They were concerned that the big players in the industry would

easily take away their ideas. The latter are better off regarding influential power, financial resources, a broader network, and an approach to the influential stakeholders in the innovation ecosystem.

Firm C engaged with the local organisations, who are the potential users. They played a vital role in developing, testing, and launching the digital platform. However, they could not decide to implement the solution in their system. The decisions needed to come from the headquarter. Consequently, the firms finalised the solutions but failed to commercialise them. Firm C's CEO expressed the difficulties his firm encountered during the innovation journey:

"We have been working with them for years, and the solution was developed together. It meets their actual needs, but the problem is, I think that even though it meets the needs of the organisation at the ground level, it may be ground level and a level up, but the decision-makers at the top don't need this themselves. The problem is that there are many different types of decision-makers, and we might not have the whole organisational interest. Just the people want to use it, but they don't want to buy it. I think there are people in the organisations who want this, but they were not the ones to make the final decisions". CEO firm C

Challenges on maintaining mutual commitment

Findings revealed that the firms struggled to include mainly the noneconomic stakeholders like NGOs, users, and influential stakeholders such as policymakers and decision-makers in the innovation process. Suppose they managed to bring them together in an engagement workshop; they find it challenging to continue engaging in subsequent phases of the innovation process. Occasionally, they did not get valuable outcomes from the engagement activities. The findings suggested that there must be a mutual commitment from the engaged participants for meaningful inclusion.

5. Discussion

We started this article by pointing out that despite the debate about the importance of inclusion in innovation, the empirical evidence that practices on the firm level are scarce (Lubberink et al., 2017; Silva et al., 2019). Innovation is an interactive process; it is obvious that firms interact with actors in the innovation ecosystem for different purposes (Fagerberg et al., 2013; Laursen & Salter, 2006; Long & Blok, 2018; Tidd & Bessant, 2020). The responsible innovation approach suggests deliberate and broad stakeholder inclusion, but whether such an approach is

suitable in real business settings remains to be questioned (Iakovleva et al., 2021; Ribeiro et al., 2018).

This study found that stakeholder engagement in innovation processes can be characterized by a spectrum of participation- from non-participation to symbolic participation to engaged participation, which correlates with earlier literature (Goodman & Sanders Thompson, 2017). While non-participation and symbolic participation can result in technically efficient outcomes, they may not contribute to accepting and using innovative solutions.

Following the innovation process, the findings showed that inclusion in the innovation process is vital in producing optimal desirable solutions Inclusion facilitated technically and ethically sound solutions. The empirical evidence thus aligned with the theorizing on the importance of the inclusion concept (Goodman & Sanders Thompson, 2017; Stilgoe et al., 2013; von Hippel & von Krogh, 2015; von Schomberg, 2013) and with some recent empirical evidence (Marschalek et al., 2022; Timmermans et al., 2020). Thus, inclusion provided a platform for need-solution interaction via experiential learning to create user-friendly solutions that bear the potential to address societal challenges.

Including stakeholders, especially the user groups, at the design stage of the innovation process allowed the firms to pivot with minimal effort and demanded less time and resource usage than during the test or early market entry stages. Broader inclusion early in the design phase provides firms with a better decision on whether or not to consider innovative ideas, which is also in line with some previous research (Flipse & van de Loo, 2018)**.** It creates access to new angles on their needs and supplies new 'sticky' stakeholder knowledge (Von Hippel, 1994), which can significantly alter and shape emerging innovation. Our cases showed how it was possible to adapt the initial digital platform and pivot quickly to address optimal desirable needs. It also saved time, resources, and uncertainty about the solutions.

Although stakeholders' and users' inclusion in the innovation process has many advantages, firms undergo several challenges in adopting and practising such approaches in the innovation process. The analysis showed that firms, especially young start-ups, are not fully adopting inclusion early in innovation despite recognized benefits from inclusion. This is consistent with previous studies on RI in the industry (Blok et al., 2015; Lubberink et al., 2019; van de Poel et al., 2020). Analysis showed that start-ups are sceptical about inclusion due to fear of information asymmetry and domination from the influential players in the innovation ecosystem. They struggled to bring stakeholder groups with higher power distance, such as healthcare policymakers or governmental bodies responsible for procurements in public health.

Further, firms also experienced difficulties reaching out to certain vulnerable user groups, especially patients in hospitals and care centres, disabled people, or patients with dementia. This is mainly because ethical approval or consent from the next of keens is required to get in touch with such vulnerable users. The start-ups need more resources to carry out administrative work and engagement activities. As our cases were also a part of the NSCC, we observed that the cluster initiatives, like Norwegian Smart Care Lab, brought diverse stakeholders and potential user groups that were otherwise difficult to access for inclusion.

6. Conclusion

In this study, we sought to explore the extent to which the RI approach is instrumental in the governance of the firm's innovation process. We specifically focused on inclusion in the firm's innovation processes in the context of health and welfare services.

Findings confirm that the RI approach and inclusion, in particular, can help a firm minimise the likelihood of negative consequences and ensure that its innovations are developed responsibly. However, the extent to which the RI approach is instrumental in the governance of firms' innovation process can vary depending on the specific context and goals of the organisation.

Firms practice different modes of stakeholder participation at different phases of the innovation process. While non-participation and symbolic participation can result in technically efficient innovative solutions, they may not be able to meet stakeholders' and users' needs and expectations. Hence, they may not contribute to societal problem-solving. However, inclusion or engaged participation can ensure stakeholders' and users' interactions resulting in pivotal moments until optimal desirable solutions result. Thus, inclusion enables technically efficient, desirable, sustainable, and responsible solutions.

Moreover, the early inclusion in the innovation process allowed early pivoting moments enabling firms to develop desirable solutions quickly, saving their time and resources. However, the firms, especially the new start-ups, faced challenges engaging influential stakeholders and certain user groups due to resource constraints, fear of information asymmetry and administrative work in getting ethical approvement and access to engage vulnerable user groups.

Overall, the RI approach can be instrumental in the governance of a firm's innovation process by helping the firm identify and address potential adverse impacts, build trust and credibility with stakeholders, and stay ahead of regulatory and legal requirements.

Managerial contributions

Inclusion enables firms to co-design and co-create innovative solutions. Although the inclusion in the innovation process seems challenging in the short run, well-managed inclusion pays off in the medium and long term. Therefore, to manage meaningful inclusion, firms need to know whom to include, how to include and at what stage of the innovation process. This is not straightforward, but firms can overcome this by thoroughly undertaking stakeholder mapping in the innovation ecosystem before implementing the inclusion strategy.

We offer a simple self-assessment tool for inclusion by suggesting that managers and entrepreneurs try to respond to the following questions: (1) Have we explored the relevant stakeholders and potential users in the innovation ecosystem? Are there any alternative approaches to be more inclusive in the innovation process? (2) Have we considered the inputs of engaged stakeholders? (3) Does engagement represent a single perspective, or were we able to reflect on different opinions? (4) Can the inclusion of a diversity of stakeholders and users be adapted in response to the answers to these questions? We believe that answering these questions would help practitioners achieve better need–solution interactions and, consequently, a more rapid and successful innovation process.

Future research

Although this study brings some new insights to the governance of the innovation process, it is not without its limitations. First, we were looking at start-up firms. Although our study employed a longitudinal design, there was not enough time at our disposal to follow firms during different stages of their life cycle. It remains to be verified in different settings and over a more extended period whether inclusion practices will result in desirable outcomes that gain broad user and market acceptance. We advise that future studies could consider larger samples using quantitative methods, studying either the same sector or different sectors to allow for generalisability.

Furthermore, future research should seek a deeper understanding of socio-cognitive sense-making while practising inclusion. Including the right people in developing innovation and knowing when and how to do so deserves more attention. What role does the digital nature

of innovation play in such an inclusion process? How to orchestrate the human and digital elements in such an inclusive, reflective process to achieve the most desirable and socially responsible outcomes is yet to be studied.

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Responsible innovation in venture creation and firm development: the case of digital innovation in healthcare and welfare services

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Responsible innovation in venture creation and firm development: the case of digital innovation in healthcare and welfare services

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ABSTRACT

The increasing adaptation of digitalisation has engendered numerous venture ideas and entrepreneurial opportunities. Many of these ideas bear the potential to address grand societal challenges. However, perceived opportunities can be elusive, especially in the context of complex problems. Opportunity confidence (OC) can be essential to venture creation and firm development. OC depends on evaluating socioeconomic, socio-ethical, and socioecological factors, which are not straightforward. Responsible innovation (RI) can be a viable approach to building OC. However, whether or how firms and entrepreneurs pursue RI to build OC needs to be clarified. Accordingly, we explore these issues through a case study of nine for-profit firms in digital healthcare and welfare services. The findings reveal that although the firms do not integrate RI principles in innovation and entrepreneurial activities per se, they practice them to varying degrees. This helps them to build OC. The study contributes to theory, practice, and policy.

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Introduction

Responsible innovation (RI) has become a hot topic on political, industrial, and academic agendas. Broadly, it refers to the governance of innovation and entrepreneurship that aligns with stakeholders' and society's needs, values, and expectations and as a way to make sure science, technology, and innovation address the major societal challenges (von Schomberg 2013). While this has dominated the policy discourse, including innovation policies (Fitjar, Benneworth, and Asheim 2019), it also applies to innovation and entrepreneurial activities. These activities can be impactful if entrepreneurs and firms are responsive to stakeholders' concerns, needs, values and expectations (Owen, Macnaghten, and Stilgoe 2012; von Schomberg 2013; Wickson and Carew 2014). Also, the RI discourse argues that public deliberation and responsiveness must be prioritised to deal with 'questions of uncertainty, motivations, social and political constitutions, trajectories and directions of innovation' (Stilgoe, Owen, and Macnaghten 2013, 1570). Areas for consideration include the anticipated positive and negative impacts of innovations,

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the societal and ethical dimensions of technological development and the inclusion of diverse stakeholders in the innovation and entrepreneurship processes (Owen 2014; Ribeiro, Smith, and Millar 2017).

Recognising the value of stakeholder inclusion in the product-development process, the application of RI in firms is often a process of governance with a strongly normative loading. Still, clear and practical guidelines for implementing it are lacking (Lubberink et al. 2017). Similarly, theoretical studies have focused on normative models of RI, and relatively few empirical studies of RI in practice in corporate settings exist (Owen and Pansera 2019; Timmermans et al. 2020). (See also Asante, Owen, and Williamson 2014 Journal of Responsible Innovation article of RI in financial services as an example) (Asante, Owen, and Williamson 2014). Thus, despite nearly a decade of study of RI in industry, its influence in business communities is still far from being fully understood. One of the reasons van de Poel and colleagues (Poel et al. 2020) indicated in their study was that companies struggle to understand the value of their investment in RI. As such, the companies do not fully appreciate how the adoption and practice of RI in innovation and entrepreneurship can enhance their goals and objectives (Poel et al. 2020). Firms could be motivated to adopt and practice RI if they see the benefits of implementing RI in enterprises.

Related to the discourse on RI, there are growing public concerns about the underlying motivations for using digital technologies in healthcare and welfare services (Owen, Bessant, and Heintz 2013; von Schomberg 2011). Arguably, the potential for digitalisation to improve healthcare and welfare benefits will depend at least in part on how entrepreneurial activities are conducted (Bessant et al. 2017; Iakovleva, Oftedal, and Bessant 2019b). Addressing these issues is neither easy nor straightforward. Healthcare and welfare service issues are complex because they involve diverse interest groups: patients, healthcare professionals at different levels and organisations (hospitals, nursery homes, GP, specialist care), equipment providers, governments and governmental institutions on municipal, regional and national levels, insurance companies, as well as entrepreneurs and innovators who come up with new products or services (Iakovleva, Oftedal, and Bessant 2019b). Therefore, a classic linear techno-scientific approach often results in rejection of the innovation due to difficulties of their integration into existing systems, scepticism from healthcare professionals or lack of user-friendliness (Timmermans et al. 2020; Marschalek et al. 2022).

Moreover, the healthcare sector is a sensitive and heavily regulated system (Oftedal, Iakovleva, and Bessant 2019). Thus, ignoring societal concerns about novel technologies can result in the abandonment of many promising ventures (Oftedal, Foss, and Iakovleva 2019). Therefore, the potential societal effects of digital technologies and digitalisation in healthcare and welfare services require detailed exploration.

Digital technologies can engender entrepreneurial opportunities (Nambisan 2017; von Briel, Davidsson, and Recker 2018) and inspire new economic activities and industries (Davidsson 2015; Parker, Alstyne, and Jiang 2017; Porter and Heppelmann 2014; Shane 2012). Moreover, if developed and deployed correctly, new ventures employing digital technologies solve many societal challenges, including healthcare and welfare services (Steinhubl and Topol 2015). In particular, digitalisation might lower the costs of healthcare services, facilitate the provision of services in remote areas, and increase the efficiency and effectiveness of care (Iakovleva, Oftedal, and Bessant 2019a). At the same time, with the growing surge in digitalisation, entrepreneurs

and firms have seen potential opportunities for new ventures and businesses within digital healthcare and welfare services. Exploiting these opportunities requires entrepreneurial initiatives to be inclusive, anticipatory reflective and responsive in order to address potential adverse societal effects that add to the chorus of concerns about the direction of innovation and entrepreneurial activities (Iakovleva, Oftedal, and Bessant 2019b)

Opportunities can be defined as a pool of venture ideas (Dimov 2010). However, not all venture ideas are good for society; concerns about the negative externalities and the dysfunctional effects of entrepreneurship are increasing (Lazonick 2014; Soete 2019; Zahra and Wright 2016). At the same time, opportunities are essential to entrepreneurship in general (Eckhardt and Shane 2003), and digital innovation and entrepreneurship (Nambisan 2017; Nambisan et al. 2017) in particular, but they are not enough to explain these phenomena (Davidsson 2015; Davidsson, Gregoire, and Lex 2018).

Recent studies have suggested that opportunity confidence (OC) might provide a better explanation than the mere presence of opportunities for entrepreneurial venture creation (Davidsson 2015; Davidsson, Gregoire, and Lex 2018; Davidsson, Grégoire, and Lex 2021). 'OC refers exclusively to an Actor's evaluation—from negative to positive—of a stimulus that may be relevant to the creation of new economic activity. It denotes not what the Actor sees but their evaluation of it' (Davidsson 2015, 685). OC provides deeper insight into the process of identifying potential venture ideas, evaluating them, and deciding to take action in the venture creation process (Davidsson 2015; Dimov 2010; Foss et al. 2008; Klein 2008). Exploring how entrepreneurial firms create OC is crucial to understanding venture success and firm development. In common with RI, firms must address users' and stakeholders' concerns and expectations to build OC (Dees and Anderson 2006; Gemmell, Boland, and Kolb 2012; Nicholls 2009).

Building OC in the context of digital technologies in healthcare and welfare services is demanding (Jirotka et al. 2017; Lehoux et al. 2018). Recent discussions on RI and its implications for innovation indicate that RI is a framework that can be crucial to building OC (cf Flipse and van de Loo 2018; Iakovleva et al. 2021; Long et al. 2020; Scholten and Van Der Duin 2015; Thapa, Iakovleva, and Foss 2019; Voegtlin et al. 2022). However, RI is still evolving. It is not well integrated into the corporate world, and industrial actors can perceive it as complicated and ambiguous (Dreyer et al. 2017; Lubberink et al. 2017; Oftedal, Foss, and Iakovleva 2019). While most of the discussion around RI relates to the governance of the research process in the university and research sector (Silva et al. 2019), we look at entrepreneurs and firms. Entrepreneurs explore and exploit opportunities and contribute to socio-economic change (Choi and Shepherd 2004; Clough et al. 2019). They are increasingly recognised as change agents (Choi and Gray 2008; Lubberink et al. 2019; Nicholls 2009). Similarly, firms are the drivers of innovation, their role in contributing to grand societal challenges is critical (Blok et al. 2015; Long et al. 2020; Thapa and Iakovleva 2019).

It is, therefore, necessary to understand whether and how firms adopt RI in the venture creation process and how the integration of dimensions of RI can contribute to OC for venture creation and firm development. Therefore, the paper seeks to answer the following research question:

To what extent does an RI approach contribute to building OC in venture creation and firm development?

Accordingly, the paper explores the extent to which RI dimensions of inclusion, anticipation, reflexivity and responsiveness contribute to building opportunity confidence of firms and entrepreneurs in new venture creation and firm development. It examines the venture creation process in general and OC specifically and the role of RI approaches in evaluating potential venture ideas that build OC to act for desirable outcomes. Overall, it contributes to the discourse on RI by addressing the value of responsible entrepreneurship.

The remainder of the paper is structured as follows. Section 2 describes venture creation in digital healthcare and welfare services and RI and its dimensions. Section 3 presents the research design. The research findings are presented in Section 4, the discussion in Section 5, and the conclusion in Section 6. Section 6 also describes the paper's contributions, the theoretical and practical implications of the findings for entrepreneurs and policymakers and the limitations of the research.

Venture creation in digital healthcare and welfare services

There is a growing belief that digitalisation can enable venture opportunities in various sectors, including healthcare and welfare services (von Briel, Davidsson, and Recker 2018). Thus, digitalisation is evolving with unprecedented velocity, offering innovators and entrepreneurs new ways of gaining knowledge, enhancing capabilities for innovation and entrepreneurship and enabling faster data collection, aggregation, and analysis (e.g. Brynjolfsson and McAfee 2014; Steinhubl and Topol 2015). Digital platforms have brought together an ecosystem of producers, users, customers, and complimentary service providers, enabling them to co-create products and services (e.g. Dufva et al. 2017; Frey, Lüthje, and Haag 2011). Furthermore, digitalisation has enabled novel functions in products with a remarkable price/performance ratio (Yoo 2010; Yoo, Henfridsson, and Lyytinen 2010). Therefore, harnessing the potential of digitalisation could enable not only new venture opportunities but also quality products and services at a reduced cost (Yoo 2010), new economic activities, new industries (Nambisan 2017; Parker, Alstyne, and Jiang 2017; Porter and Heppelmann 2014) and solutions to grand societal challenges (Christensen and Fogg 2017; Dufva et al. 2017).

There has been a surge in venture creation of digital artefacts, platforms, and infrastructure by entrepreneurs and firms in the digital healthcare and welfare service sector (Nambisan 2017; Parker, Alstyne, and Jiang 2017; Porter and Heppelmann 2014). eHealth, defined as the use of modern information and communication technologies to meet the needs of citizens, patients, healthcare professionals, healthcare providers, and policymakers (European Commission 2016), can be taken as an example.

The ultimate goal of entrepreneurship is to create new ventures that stimulate economic development and employment and provide profits for their shareholders. Despite its increased recognition as a driver of economic development, concerns have been raised due to the adverse effect of entrepreneurship in society (Nicholls 2009; Zahra and Wright 2016). This is especially true for digital healthcare sector, where ventures within digital healthcare and welfare services can create negative impacts, such as

public concerns about privacy and security due to digitalisation (Hofmann 2013; Jirotka et al. 2017). Thus, entrepreneurship scholars have raised concerns about how opportunities are discussed and interpreted in entrepreneurship research (Davidsson 2015; Eckhardt and Shane 2003; Klein 2008; Gras et al. 2020; Scheaf et al. 2020).

The interpretation of opportunities can be ambiguous and even elusive in complex problems, especially in healthcare and welfare contexts (Davidsson 2015; Hsieh, Nickerson, and Zenger 2007; Gras et al. 2020). Entrepreneurs see opportunities and take actions that might not achieve desired outcomes or abandon potential opportunities that bear socio-economic values. OC has been proposed as an important construct in the venture creation process. It makes one of the four primary constructs of the venture creation process, thus, alongside venture ideas, action and outcomes (Davidsson 2015). Although all the constructs are vital in the venture creation process, OC is crucial since it largely determines its success. It denotes entrepreneurs' evaluation of venture opportunities (Davidsson 2015). It depends on different socio-economic, socio-ethical and socioecological factors (Gemmell, Boland, and Kolb 2012) key to developing belief in the feasibility of the opportunity and start-up self-efficacy (Dimov 2010). For example, opportunity feasibility belief depends on the ability of entrepreneurs and firms to make customers, users and stakeholders believe in their offerings and gain confidence in attracting resources essential to building competitive advantages over others (Dimov 2010; Eckhardt and Shane 2003). Similarly, start-up self-efficacy is the entrepreneurs' and firms' confidence regarding creating new ventures (Bandura 1982; Dimov 2010) and can be enhanced through social interactions and mutual and experiential learning (Gemmell, Boland, and Kolb 2012; Kolb and Kolb 2009; Lorsbach and Jinks 1999; Timmermans et al. 2020). The rationale is that the entrepreneurial actions taken with OC will likely lead to desirable outcomes since it facilitates the evaluation of venture ideas available to entrepreneurs.

It is increasingly recognised that entrepreneurial success depends on whether or not the solutions offered by the firms meet the needs, values and expectations of the users, customers and stakeholders in the entrepreneurial ecosystem (Zahra and Wright 2016). Further, the adoption of solutions provided by entrepreneurs and firms depends on the users', customers' and stakeholders' perceived confidence about the solutions and belief that offered products would solve their problems (Bowen and Chen 2001). Moreover, Kuester, Konya-Baumbach, and Schuhmacher (2018) argue that users' and consumers' adoption of a product or service relies on their trust in the entrepreneurial firms producing and offering it. Thus, building OC for socially responsible venture creation and sustainable firm development, entrepreneurs and firms need to consider not only the positive externalities but also the adverse or dysfunctional effects of entrepreneurial activities in society (Zahra and Wright 2016). How firms and entrepreneurs develop OC in the context of digital healthcare and welfare services is unclear and needs further exploration. RI could be a viable approach in this context.

Responsible innovation (RI)

According to Stilgoe, Owen, and Macnaghten (2013), 'Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present' (1570). RI is about collectively directing innovation and entrepreneurial

trajectories to align them with the values, needs and expectations of stakeholders and society at large (Owen et al. 2013; von Schomberg 2013). For this purpose, integrating the dimensions of the RI framework—inclusion, anticipation, reflexivity and responsiveness (Stilgoe, Owen, and Macnaghten 2013) in venture creation and business development is an emerging approach (Iakovleva, Oftedal, and Bessant 2019c).

Inclusion dictates that stakeholders and the public be engaged as soon as innovation and entrepreneurial activities are initiated (Owen, Macnaghten, and Stilgoe 2012). It allows active democratic participation, which brings knowledge diversity to the problem of identifying and agreeing on the most necessary steps to take to alleviate social and environmental issues. Entrepreneurs should ensure the inclusion of a broad group of stakeholders from the very beginning of the innovation and entrepreneurial process, including representatives of the public sector, non-governmental organisations, citizen groups, users and customers. Such inclusion facilitates broader knowledge accumulation on society's needs and integrates the views and interests of different societal actors. It provides a platform for open innovation (Chesbrough 2006; Long and Blok 2018) and helps entrepreneurs to identify potential venture ideas (Davidsson 2015), builds consensus for legitimacy (Irwin 2006; Hajer 2009) and provides opportunities for diffusion (Asveld, Ganzevles, and Osseweijer 2015) of products and services.

Anticipation consists of systematic thinking about the potential intended and unintended consequences of a particular innovation or venture (Guston 2014). It encourages critical thinking about possibilities, opportunities and feasibility (Martin 2010; te Kulve and Rip 2011). Anticipation should be directed not just to questions of financial risk or gain but also to the positive and negative externalities of innovation and entrepreneurial activities in society at large (Zahra and Wright 2016).

Reflexivity in the innovation and venture creation process is about the value proposition offered to the stakeholders, environment and society (Stilgoe, Owen, and Macnaghten 2013). Entrepreneurs and firms need to be mindful of their value propositions. Exaggerating them creates higher expectations in customers, users, and stakeholders. Failing to meet those expectations when the product or service is introduced would shake stakeholders' confidence in the venture, reducing its likelihood of success. Therefore, reflexivity is essential in establishing and maintaining sustainable relationships in networks, collaborations, and partnerships. Reflective entrepreneurs are more likely to build their societal image and reputation (Lee and Kim 1999; Stahl 2013).

Responsiveness is the willingness of innovators and entrepreneurs to show respect and care towards stakeholders and societal actors during venture creation and business activities (Meijboom, Visak, and Brom 2006). It enables co-responsibility when shaping need-based ventures for alleviating societal problems. Social expectations of businesses have changed, and entrepreneurs must change their value creation horizons to incorporate societal and environmental well-being in addition to profit (Zahra and Wright 2016). Venture creation attempts merely incentivised by entrepreneurial opportunity might lead to venture failure and result in a lose-lose situation for entrepreneurs and society.

Despite the potential benefits of integrating RI policies into innovation and entrepreneurship, it remains unclear how RI can be employed in a firm's everyday activities (Armstrong et al. 2012; Blok et al. 2015; Dreyer et al. 2017; Lubberink et al. 2017).

For RI practices to become part of innovation and entrepreneurial processes, firms and entrepreneurs must know why and how such practices should be adopted and what value such initiatives add to them (Long and Blok 2018).

For this study, we considered two aspects of integrating RI dimensions into innovation and business activities. First, we focused on assessing the extent to which RI is practiced by firms and entrepreneurs in new venture creation and firm development. Secondly, we examined how the RI approach facilitates building OC in venture creation and firm development.

The potential role of RI and OC in venture creation and firm development

Despite their contributions to economic development, employment and social well-being, firms and entrepreneurs are criticised for not doing enough for society at large (Lazonick 2014). There is growing sentiment that entrepreneurs need to take social responsibility for their products and services and move beyond profit maximisation to consider the intended and unintended consequences of their entrepreneurial activities (Owen et al. 2013; Zahra and Wright 2016). Due to the increasing negative externalities of innovation and economic activities in society, such as climate change, public health and disparity, concerns have been raised about societal values, risks, and benefits of innovation and entrepreneurship (Thapa, Iakovleva, and Foss 2019). If these concerns are not addressed, there is a danger that an already existing crisis of mistrust of stakeholders and users towards the business community could hinder the adoption of innovative solutions (Dreyer et al. 2017). Therefore, innovators and entrepreneurs must align their innovation and entrepreneurial activities with society's values, needs, and expectations to avert any danger of losing stakeholders' and public trust in innovation and entrepreneurship in the wake of widening grand challenges (Ashworth et al. 2019; von Schomberg 2013). This also means that firms and entrepreneurs need to consider socio-economic, socio-ecological and socio-ethical factors in venture creation and firm development activities (Flipse and van de Loo 2018; Long et al. 2020; Zahra and Wright 2016).

Therefore, start-ups and incumbent firms need to identify, understand, and critically evaluate the potential social benefits and hazards of innovation and entrepreneurial activities (Markus and Mentzer 2014; Zahra and Wright 2016) before making decisions about venture creation. Failing to consider the socio-economic and socio-ethical factors in venture creation and firm development activities will affect firms and entrepreneurial success (Brand and Blok 2019).

Arguably, firms and entrepreneurs need to build OC to evaluate the opportunities resulting in successful and sustainable ventures. While social interaction is the base to build OC (Gemmell, Boland, and Kolb 2012), the dimensions of RI principles can play an instrumental role. Thus, they may help evaluate socio-economic, socio-ecological and socio-ethical factors to build OC that enables sustainable and responsible venture creation and firm development (Long and Blok 2018; Lubberink et al. 2019; Wickson and Carew 2014; Voegtlin et al. 2022).

The inclusion of a diverse range of stakeholders and users early in the venture creation process allows entrepreneurs and firms to identify heterogeneous expectations, needs and concerns (Stilgoe, Owen, and Macnaghten 2013; von Schomberg 2013). It provides access to a diversity of expertise that may be crucial in venture creation and

firm development. The direct interaction with a diverse group of stakeholders, customers and users provide knowledge about the reverence of venture ideas, access to potential collaboration, networking, resources, experiential learning environment and refinement of their venture ideas (Timmermans et al. 2020; Marschalek et al. 2022). Moreover, inclusion enables the communication of otherwise inaccessible tacit knowledge (Shane 2000; Carayannis and Campbell 2014), resulting in the co-creation of potential solutions to societal problems (Long and Blok 2018). The deliberate inclusion of stakeholders and potential users, on some occasions, empowers vulnerable stakeholder groups (Brand and Blok 2019; Iakovleva, Oftedal, and Bessant 2019a). These opportunities will facilitate firms and entrepreneurs in developing feasibility beliefs about the products and services, ultimately increasing venture success (Davidsson, Gregoire, and Lex 2018; Dimov 2010).

Anticipation enables entrepreneurs and firms to make subjective judgments about the potential consequences of venture ideas that go beyond financial risk to include societal and environmental risks (Guston 2014). It allows them to foresee alternative solutions (Martin 2010; Gudowsky and Peissl 2016) that are desirable and enhance the impact of the innovation and ventures (Rhisiart, Störmer, and Daheim 2017). Arguably, anticipation allows firms and entrepreneurs to think out of the box and will enable them to critically consider the unintended consequences of their innovation and ventures in society beyond financial profit and loss. Further, it keeps firms and entrepreneurs updated with the expectation of the stakeholders and users in the entrepreneurial ecosystem. Thus, anticipation enhances product and service efficacy and self-efficacy to decide and launch the venture confidently.

Reflexivity enables entrepreneurs and firms to keep themselves open and transparent about their capabilities and activities in venture creation and firm development (Weber and Rohracher 2012). Reflexive firms and entrepreneurs can maintain trustworthy relationships among stakeholders and users, ensuring their support and increasing the likelihood of adaptation of their product and services (Asveld, Ganzevles, and Osseweijer 2015; Kuester, Konya-Baumbach, and Schuhmacher 2018). Further, reflexivity aids firms and entrepreneurs in reputation building (Lee and Kim 1999; Stahl 2013) and enhances the stakeholders', users and potential users' confidence about their offerings which enables in adoption and diffusion of their products and services (Bessant et al. 2017; Rogers 1995). Thus, reflexivity can ensure firms and entrepreneurs' feasibility belief about the ventures and enhance self-efficacy belief in venture creation and firm development.

Finally, responsiveness enables entrepreneurs to develop a dynamic capability (Eisenhardt and Martin 2000; Teece, Pisano, and Shuen 1997) to provide solutions to grand societal challenges and stakeholders and users' needs and expectations in ways that go beyond their legal obligations (Owen et al. 2013; Pellizzoni 2004; Pellizzone et al. 2015). Responsiveness allows firms and entrepreneurs to listen to the concerns of stakeholders and users very carefully and enables them to take care of their users and stakeholders (Stilgoe, Owen, and Macnaghten 2013). Through responsiveness, firms and entrepreneurs can enhance their reputation in society and establish themselves as responsible entities, enhancing their sustainability (Wicks and Berman 2004). Thus, responsiveness enhances their feasibility and efficacy belief in venture creation and firm development.

Research design

The aim of this study is to explore the extent to which firms and entrepreneurs practice RI in venture creation and firm development, and whether RI practices facilitate to build OC. The context of the study is digital healthcare and welfare services. Both RI and digital venture creation in healthcare and welfare services are new and emerging fields. Both these social phenomena warrant a detailed understanding of how firms and entrepreneurs practice RI dimensions in venture creation and business development and how such incentives enable them to build OC in socially responsible and sustainable ventures and firm development (Yin 2014).

Therefore, we chose an explorative qualitative approach (Edmondson and McManus 2007) and employed a multi-case study design to carry out in-depth investigation and data triangulation from multiple sources, including secondary data sources (Eisenhardt 1989; Eisenhardt and Graebner 2007).

Case selection and data collection

We considered nine firms at different life stages, including three start-ups, three recently launched ventures and three established firms. The firms are part of the 194 members of the Norwegian Smart Care Cluster (NSC), located in the Stavanger region in Norway and engaged in digitalising healthcare and welfare services. S1, S2 and S3 are Start-ups at the prelaunch stage that are prototyping and testing their products or services. L1, L2 and L3 are Start-ups at the launched stage that have moved beyond the testing phase to launch products into the market. Established firms have recognised products on the market. E1, E2 and E3 are established firms promoting digital healthcare and welfare products and services as a separate business unit or have introduced it as an incremental innovation by incorporating digital components such as software or additional hardware into existing products. Our purpose in adopting multiple case studies was to understand the similarities and differences between the cases and enable us to analyse data within and across cases (Gustafsson 2017).

The cases were selected following a purposive sampling strategy (Patton 2002), adopting the following criteria: (1) Start-up firms or innovative projects within small or medium-sized firms in the early stage of development. (2) All the firms engaged in digital innovation in healthcare and welfare services. The head of NSCC provided a list of 20 firms meeting our criteria. We contacted all the firms, and nine firms showed a willingness to participate in the research project. Table 1 provides an overview of the case firms participating in this study.

Data were collected longitudinally through two rounds of semi-structured in-depth interviews with CEOs and project managers of the firms and other stakeholders associated with eHealth promotion in the region. In the first round, between autumn 2016 and spring 2017, we conducted 11 interviews with nine firms and 14 interviews with other actors associated with healthcare and welfare service innovation in the region. We chose CEOs and project managers, and directors for the interviews. We believe they could better reflect on their experiences, approaches and strategies in venture creation and firm development. The other actors included representatives from a regional cluster of firms in welfare technologies, employees of home care services that use

Table 1. Description of the case firms, their status and sources of data.

Firms	Established	Products/Services	Purpose	Target groups/ customers	Interview[a] data Round 1	Interview data Round 2	Status
S1	2015	Digital Platform where care providers, administrators and external suppliers of e-learning materials interact and update their knowledge and monitor their progress.	Competence building	Healthcare workers	CEO and Project manager	CEO	Start-up pre-launched
S2	2014	Digital application (app) for collecting and owning personal experience data that can be shared or even traded.	Empowering Users	Publics	Project manager	Project manager and CEO	Start-up pre-launched
S3	2016	Digital platform for interaction and coordinating services.	Coordination competence building	NGOs and volunteer organisations in healthcare services	CEO	CEO	Start-up pre-launched
L1	2012	Digital self-health assessment application (app) for monitoring lifestyle to improve and maintain physical and mental well-being.	Healthy and active living	Students, employees, senior citizens	CEO	CEO	Start-up launched
L2	2015	Smartwatch-based automatic health alarm with two-way communication capacity in a compact package.	Minimising health risk	Individual user	CEO	CEO	Start-up launched
L3	2012	GSM-and GPS-based security alarm.	Safety solution	Older citizens living alone at homes/ care homes	Project manager	Project manager	Start-up launched
E1	1998	Digital platform for clinical collaboration and security services	Quick, improved quality and cost-effective healthcare delivery/ e-health	Offshore businesses	Project manager	Project manager	Established
E2	1980	Integrated digital comments in comfort wheelchairs/ smart wheelchairs.	Independent living	Handicapped individuals	CEO	CEO	Established
E3	1940	Integration of digital components to patients' simulators for increased risk-free training in emergency care.	Help save lives	Healthcare professionals Healthcare educators Publics	Technical director-patient care & Project manager	Technical director & Quality assurance (QA) director	Established

[a]Interview data of 14 stakeholders in round 1 and 2 stakeholders in round 2 were also included. The stakeholder group is common for all the firms since they are from the same region and same cluster.

welfare technologies and the head of a regional strategic planning organisation. In addition, the president of a retirement organisation was interviewed as a representative of retired older people; retirees represent a significant number of potential digital healthcare and welfare service users. Each interview lasted for 60–80 min.

The second round of interviews was conducted a year later, in 2018–19. It comprised 11 interviews (40–60 min each), nine with the case firms and two with other stakeholders. In the second round, we interviewed the same individuals as in the first round, except for firm S3, where we interviewed the Quality assurance (QA) director as recommended by the previous interviewee. The purpose was to share our analysis from the first interview and get updated information associated with venture creation and firm development activities. The two new stakeholders were identified as influential in the digitalisation of healthcare and welfare services and interviewed.

All the interviews were recorded with permission from the interviewees. In addition to the interviews, we collected secondary data from the firms' home pages, documents and presentations they provided and press releases about their products and services. Data were also collected from official documents on eHealth policy and future healthcare policies in Norway, two international eHealth conferences, two international smart-city conferences hosted in Norway and three regional workshops related to the digitalisation of healthcare and welfare services.

The semi-structured interviews provided a relatively open method for collecting data. As part of the interview, participants were asked to reflect on narratives of their venture creation and firm development processes. They were then asked specific questions to reflect on their motivation and engagement approaches, value proposition and responses to stakeholders' concerns about their offerings to understand the integration of RI and its implications for venture creation and business development activities. The additional data provided stakeholders' and users' opinion about digitalisation of healthcare and welfare services, firms engaged in digital innovation in this sector and their offerings.

Data analysis

The audio-recorded interviews were transcribed verbatim, allowing analysis of the transcripts.

We used a manual coding approach (Saldana 2015) to code the contents of the transcriptions. Initial coding involved searching for references for RI dimensions of inclusion, anticipation, reflexivity and responsiveness. Specifically, examining nuances like who was included in the venture creation and when, what they perceive about the unintended consequences of their product and services, the motivation behind venture creation, their value proposition and how they respond to the users' and stakeholders' values, needs, concerns and expectations based on their feedback. Next, sub-themes were drawn out under the different RI dimensions and how they facilitated OC in venture creation and firm development. We inspected the themes for internal and external homogeneity across the codes and the entire data corpus to ensure that relevant data was not omitted. Finally, we chose data excerpts to include in the presentation of the results to augment the transparency and trustworthiness of the analysis.

Findings

In this study, we investigated the entrepreneurial activities of nine firms operating in the digital healthcare and welfare service sector to explore the value of applying the principles of RI in firms and examine whether such initiatives facilitate them in building OC. In this section, we will discuss the findings of firm practices alongside four RI dimensions: inclusion, anticipation, reflexivity and responsiveness. Both advantages of such practices and challenges related to implementing these practices will be highlighted.

In line with previous studies on RI in the industry (e.g. Blok et al. 2015; Long et al. 2020; Lubberink et al. 2017; Stahl et al. 2017), our findings also suggest that all the firms studied were not familiar with RI principles per se. However, looked at through the lens of RI, they integrate and practice RI dimensions of inclusion, anticipation, reflexivity and responsiveness to varying degrees. Furthermore, like previous studies(e.g. Blok et al. 2015; Dreyer et al. 2017; Oftedal, Foss, and Tatiana Iakovleva 2019; Poel et al. 2020), we identified several obstacles to the adaptation and practice of RI in venture creation and firm development processes, especially in the case of early-stage start-ups.

Table 2 shows how firms and entrepreneurs, in our cases, practiced inclusion, anticipation, reflexivity, and responsiveness. We viewed such practices through the lenses of six pillars. The first pillar refers to 'who': who was involved in the four above-mentioned RI dimensions. The second is 'when': at what stage of the entrepreneurial journey these processes happened? Further, we considered 'what': what was included, anticipated, reflected, and responded to. Then, we considered the 'how': how firms practiced these RI activities. Finally, we clarified the 'outcomes' and 'implications for Opportunity Confidence': what such RI activities resulted in and how such practices facilitated building OC in innovation and entrepreneurial activities.

We will now explain the table by considering firm practices of the four dimensions of RI: inclusion, anticipation, reflexivity and responsiveness and how such practices lead to building OC in venture creation and firm development.

Inclusion: The firms studied include a range of stakeholders in venture creation and business development activities. They engage stakeholder groups in varying degrees. For example, firms L2 and L3 have mainly customers, investors, suppliers, designers, and experts in their networks. Others extended their networks to include users and potential users as well. In the case of firms S3 and L3, however, the firms considered their priorities in weighing the inclusion of stakeholders, choosing those they believed could directly add value to their ventures or the company's development and whom they perceive to be trustworthy. The entrepreneurs and firms practised stakeholder inclusion through workshops, opinion polls, open innovation, and open networking approaches.

All the firms indicated that engaging diverse stakeholder groups allowed them access to knowledge about the perspectives of those stakeholders: their needs and expectations and their attitudes towards innovative venture ideas. Inclusiveness enabled firms to be closely acquainted with stakeholders' needs, opinions, and expectations about the solutions. It allowed the firms to know the feasibility and scope of their offerings from diverse perspectives. As the quality assurance (QA) director of firm E3 emphasised the value of inclusion:

> Mapping the customer journey is all about identifying customers' need, and really understand what customers' needs because asking the customers not always sufficient. We need

Table 2. Findings on RI practices and contribution to building OC in venture creation and firm development.

RI dimension	Who	When	What	How	Outcomes	Implications for Opportunity confidence
Inclusion	Customers Experts Consumers/Users Investors Potential users Next of kin of potential users	At different stages of venture creation	Ideas, opinion, emotions, knowledge and experience	Workshops Surveys Open innovation Open network Crowdsourcing	Access to new knowledge/ resources Experiential learning Knowledge Sharing/creativity Mutual benefits Empowerment	Feasibility belief: knowledge, resources, potential success, alternatives options, investment, partnership, collaboration opportunities Self-efficacy belief: Mutual and experiential learning, interactions Trust building Reputation
Anticipation		Mainly at the beginning	Risk Privacy Uncertainty Safety Expectations Potential benefits	Forecasting Scenario analysis Probability Technology assessment	Awareness of consequences, but mostly limited to financial risks	
Reflexivity		Throughout	Purpose Motivation Scope Quality Value	Business model Mission statement Impact	Customer relationship Support Ripple effect	
Responsiveness		At different stages, but most commonly in the testing phase	Users and stakeholders' feedback concerns worries	Change in design Constant modification and improvement of products Chang in business models	Mutual understanding Respect Care Adaptive capability Dynamic capability	

> to go out, observe and spend time with them to really understand their needs. QA Director, E3.

Similarly, the firm S1 introducing an e-learning platform for healthcare workers explained their purpose of stakeholder and user inclusion in their venture creation process:

> The system they had in oil sector or other sectors through years and years, you can't just transform that to home or care sector. You need to ask them what they need because you have to start from scratch and get the system that adapts well in everyday life and their work today. CEO, S1

The inclusion of stakeholders and users in the venture creation process could provide mutual benefits for the firms and stakeholders. The stakeholders and users who were frustrated not getting the solutions to their needs and expectations thought that engaging with firms developing solutions could benefit both. The health educator, one of the influential stakeholders in the healthcare and welfare sector, expressed her thought:

> I want them to make something that I can use. I am more interested in helping them, making something that I can actually benefit from and actually use in my tutoring to students. Health Educator

Data analysis also showed that firms include stakeholders at different stages of their venture creation process. Those who managed to have a diversity of stakeholders, including the users' group, were advantaged by getting the opportunity of familiarising with the root cause of the problems and appropriate solutions early on, accumulating confidence of appropriateness of their offerings to the users, customers, and stakeholders. Firm E shared the significance of user inclusion while developing solutions:

> We have user-centred teams because our thinking is that this team is responsible for these users and they have continuity in the team, they regularly go out and visit customers, getting feedback, and over time, they would build that understanding of customers. So, that again reduces the chances of going all wrong with the products. Technical director, E3

The stakeholders' information, particularly at the beginning of the venture creation process, provided significant value for the firms as they were the sources of knowledge and inspiration to continue their ventures. In some cases, the inclusion of diverse stakeholder groups early in the ideation phase enabled firms to develop solutions in collaboration with the experts, users, and service providers. They leveraged these opportunities to co-design products, make users and stakeholders more confident about their solutions and even empower users.

Firm L1 shared their failure story of trying to push the solutions to users and how they succeeded by users' inclusion in designing and testing the solutions.

> When we introduced a digital self-assessment platform for the employees in municipalities, they did not like our solution. Instead, they preferred the traditional paper version. However, they began to love it when we worked closely with them and designed the platform accordingly. CEO, L1

Firm E3 also shared their success story of new product development through the early inclusion of users in the venture creation process:

> Without working together with our partners, who are experts in emergency care and users of our solutions, we would not have been able to develop such successful solutions for emergency care. Project director, E3

However, in some cases, firms L2 and L3, for example, the entrepreneurs and firms, seemed to overlook the inclusion of users earlier in the venture creation and firm development process. Users are a marginalised stakeholder group with the least decision-making power in these cases. In other words, they are considered passive recipients of the solutions. Hence, they were included in the testing or launch phase to assess the efficacy of a product and gain legitimacy for it. However, as a result of such late inclusion, the potential users in these cases denied the acceptance and adoption of the first version of innovative solutions since the products did not meet users' expectations regarding the products' design. The firms needed to redesign and reproduce the product to their specification, which incurred firms extra time and investment.

Data analysis also revealed that some of the firms, especially the early start-ups with limited access to resources and external knowledge networks, are unable to invest in engagement activities, despite recognising the benefits of a diversity of stakeholders and users in the venture creation and firm development process.

In some cases, for instance, in firm S3, the entrepreneurs were hesitant to include influential corporate actors whom they perceived as competitors in their network. They feared that they would steal their ideas and lose their opportunity.

Further, as noted in the case of firms S3, L1 and L2, entrepreneurs felt that interacting with policymakers and decision-makers who had the purchasing power in municipalities was very challenging. First, firms experienced difficulties in getting access to the decision-makers. In the cases mentioned above, influential stakeholders (policymakers and decision-makers) either turned down the firm's invitation showing their busy schedules or cancelled the meetings at the last minute. Thus, firms believe they have no or negligible influence on such decision-makers. During our study, we also interviewed influential stakeholders. We found that healthcare and welfare service providers often do not believe in the product efficacy offered by early start-up firms. They feel responsible for providing robust and proven solutions to citizens with at least three years of track record. For many entrepreneurs, such a condition was an impossible requirement.

Anticipation: The firms we studied anticipated risk. Despite major concerns about risk on investment, many firms and entrepreneurs expressed concern over the impact their solutions will have on the public.

> If appropriately implemented or used as tools to facilitate healthcare technologies, it could save time and resources, increase efficiency, and increase the level of emergency care. Technology can be a support mechanism in healthcare since it facilitates resource allocation to improve healthcare quality. Health educator

The quote illustrated the need and expectations of stakeholders who were also potential users of digital healthcare and welfare technology. It indicates that the firms should anticipate stakeholders' and users' needs and expectations. Further, they need to anticipate the unintended impact of digital technology and reflect on the measures they are taking to prevent possible damage due to the implementation of technologies in society.

Data analysis indicated growing practices among the case firms and entrepreneurs on anticipation beyond financial risks including unintended consequences that the digital

technologies might cause to the stakeholders and users. Therefore, the firms and entrepreneurs anticipate the privacy, security, and ethical issues accompanying digitalisation. They have adopted different forecasting, scenario analysis, probability, and technology assessment strategies. Moreover, case firms have thought about backup solutions to overcome the negative consequences that might cause due to the digitalisation of services.

> With all this data, you would have to plan for privacy. How will you handle it? and the way we have solved it is that the customers owe their data. Also, we are using encryptions and blockchain technology to keep it safe. Manager S2

Data analysis also showed that anticipating and reflecting on alternative solutions to overcome the undesired effects of digitalisation can enhance security, transparency, traceability of shared data, and trust across entrepreneurial ecosystems. Thus, anticipating socio-economic and ethical risk enabled product or service adoption confidence among the potential users and stakeholders. Also, it helped firms and entrepreneurs develop OC about the service efficacy and feasibility of new ventures and businesses.

Reflexivity: The entrepreneurs came up with venture ideas from their own experiences, as in the case of S2, L2 and E2. Firms S1, L1, E1 and E3 got the venture ideas from their professional experiences. The venture ideas of the firms S3 and L3 came from customers' needs. All the venture ideas aimed to promote healthcare and welfare services in the region and contribute to the socio-economic transformation of the region.

Further, the firms and entrepreneurs are reflective in their value propositions to the stakeholders and users, although the degree of reflexivity varies. Some firms emphasised and reflected on the technical efficacy of their solutions but overlooked other issues associated with healthcare efficacy. Others exaggerated the efficacy of the solutions they developed. From the perspective of healthcare experts, these firms had overstated their value propositions—and this can be problematic because they cannot live up to the promises they initially made. These firms managed to convince their customers and investors to a certain extent but failed to convince healthcare workers, experts and users. However, many firms believed they could retain good relationships with stakeholders and users as long as they were reflexive in their commitments. Firm E3 elaborated on how they reflect on their value propositions to the stakeholders:

> Our key challenge is to deliver on time and cost. Some of us thought it was not ready to deliver, but the push was so hard that we must because we promised to. So, we shipped around forty units and discovered problems later. (… .). The thing is that it is acceptable as long as you do it in the right way. You respect your customers, inform them, visit them and fix the problems. QA Director E3

Data analysis revealed that the reflexive firms and entrepreneurs could maintain a trust relationship that enabled certainty about venture and business development feasibility.

As the project manager of firm E1 expressed his experience of winning stakeholders' trust and support being reflexive on the efficacy of their offerings:

> The senior management team was sceptical about our value proposition. However, when we demonstrated that it works efficiently, they trusted our solution and decided to implement it. We always focus on the quality of our services and customers' satisfaction. This is the reason why we could retain our high customer retention rate. Project manager (E1).

Data analysis revealed that case firms value openness and transparency in their value propositions to the stakeholders and users. As clearly specified by one of the respondents:

> We are not making medical equipment; that is very important to know. Our equipment is to make people feel more secure. CEO, L2.

Responsiveness: All the firms expressed a commitment to take care of stakeholders' concerns and acknowledged the importance of responding to their concerns. They emphasised the importance of addressing the stakeholders' concerns to retain customers, establish the brand reputation and increase impact and profits through innovation and entrepreneurship. Many emphasised their responsibility to take care of others beyond profitability. Firms respond to stakeholders' and users' needs, concerns and expectations by constantly modifying product or service design and business models. Their response to pivot from the original decisions was based on stakeholders' and users' feedback and specifications. For instance, several times, firms S1, S2, L2, and E3 changed product design. Firms S3 and E3 modified their business models. Firms meant that they need to do their best to address stakeholders' and users' concerns, worries and expectations until they are addressed, which was described by the respondents:

> We work together with our customers and constantly design and redesign our solution as per their feedback and recommendation, CEO, Firm S1.

> Embrace customers' responsiveness as this is to work very close to the customers to meet the challenges we have and listen closely to what we can help with. This is highly focused. Project manager, E3

Firms also mentioned that they could develop better solutions refined and developed with constant feedback from the stakeholders, which are more desirable as specified by another respondent:

> The customer was expecting an app which we had just mentioned to them … they wanted another localisation unit that they had already used from another firm, so we decided to implement that product as well in our portfolio, Project manager, Firm L3.

In the case of firms S1, L1, L3, E1 and E3, being responsive to stakeholders' and users' values, needs, concerns and expectations enabled firms to design and develop solutions that could address stakeholders' and users' problems. Firm L1 explained that it gained many new customers and users through existing users, a ripple effect in spreading and recommending solutions to peers and organisations.

Discussion

The aims of our study were, first, to assess the extent to which firms and entrepreneurs practice RI in venture creation and firm development processes. Our second aim was to analyse whether such practices facilitate building OC. The context of our study is digital innovation and entrepreneurship in the healthcare and welfare service sector in the Western region of Norway. We now discuss each of these aims in light of our findings.

Our review of the literature articulated that firms and entrepreneurs should adopt and practice RI principles in innovation and entrepreneurial activities to achieve ambitious goals of RI (Flipse and van de Loo 2018; Lubberink et al. 2017; Stahl et al. 2017; Brand

and Blok 2019; Blok et al. 2015). However, the industrial community do not fully appreciate how RI can enhance their goals and objectives (Lubberink et al. 2019). Many still struggle to understand the value of their investment in practising RI (Poel et al. 2020). One of the reasons that the literature highlighted and our findings revealed is that many firms are unaware of the term RI (Blok et al. 2015; Lubberink et al. 2017; Poel et al. 2020). Further, the literature emphasised that RI should stem from existing business practices, not a completely new and complicated approach (Dreyer et al. 2017; Long and Blok 2018; Poel et al. 2020; Long et al. 2020). Moreover, they should see the perceived benefit of adopting and practising RI in innovation and entrepreneurial activities (Poel et al. 2020). This study, thus, brings to the fore the way firms and entrepreneurs can integrate RI and the need for them to pursue the RI approaches in venture creation and business development.

Our analysis suggests that despite low awareness of the RI term itself, firms and entrepreneurs practice RI dimensions of inclusion, anticipation, reflexivity and responsiveness in venture creation and firm development. They engage with diverse stakeholder groups in the entrepreneurial ecosystem, anticipate risk, uncertainty, and alternatives, reflect on the purpose of ventures and respond to the stakeholders' and users' values, needs and concerns. However, the degree of RI practices among the case firms varied and was influenced by their resources, motivation and access to the external networks (Blok et al. 2015; Dreyer et al. 2017; Oftedal and Foss 2019; Poel et al. 2020). Besides, a lack of commitment, especially from the influential stakeholders, to engage in innovation and entrepreneurship can challenge RI practices. A mutual commitment between firms and stakeholders is essential to successfully implementing the RI framework.

Our sample cases suggest that increasing acceptance and adoption of digitalisation engenders numerous venture ideas (von Briel, Davidsson, and Recker 2018). These ideas can contribute to grand societal challenges, such as healthcare and welfare services (Peeters et al. 2016), if developed and deployed responsibly (Jirotka et al. 2017). It also means entrepreneurial opportunities (Nambisan 2017). However, the opportunities associated with these innovations can be elusive, especially in the case of complex problems (Davidsson 2015; Gras et al. 2020). It may be necessary to build OC to ensure that these ideas can be realised in socioeconomic, socio-ethical and socio-ecological value creation through successful venture creation and firm development (Davidsson 2015; Davidsson, Gregoire, and Lex 2018; Davidsson, Grégoire, and Lex 2021). Therefore, developing OC for successful venture creation and firm development will be critical in the context of healthcare and welfare service sector (Gras et al. 2020). Failing to assess the opportunities can lead to overconfidence, tempting to invest in a venture that may bear a higher risk of failure (Koellinger, Minniti, and Schade 2007). Moreover, there is a danger that entrepreneurs might abandon the promising venture ideas due to misjudgement of their capability to carry out the ventures (Dimov 2010; Scheaf et al. 2020). OC is enhanced by socioeconomic factors and social interactions (Gemmell, Boland, and Kolb 2012). Our sample focused on the roles of the RI framework in OC building activities in venture creation and firm development. It expanded the understanding of this social phenomenon. Further, our work explores that RI dimensions of inclusion, anticipation, reflexivity and responsiveness provide a mechanism to build OC beyond proving technical feasibility and efficacy to include socio-ethical feasibility and efficacy.

Our analysis illuminates that all four dimensions of RI, inclusion, anticipation, reflexivity, and responsiveness, practiced iteratively, facilitate OC in venture creation and firm development. By including the diversity of stakeholders and users early in the venture creation process, firms and entrepreneurs can access heterogeneous needs, concerns, and expectations of stakeholders and users (Owen et al. 2013; Stilgoe, Owen, and Macnaghten 2013). They can learn closely about the root cause of the problems and the frustrations that the users and stakeholders face with the existing solutions (Gemmell, Boland, and Kolb 2012; Timmermans et al. 2020; Marschalek et al. 2022). Further, firms and entrepreneurs get access to knowledge, expertise, external resources and collaboration opportunities to support the further development of venture ideas (Thapa, Iakovleva, and Foss 2019). Moreover, the inclusion of users early in the venture creation process enabled entrepreneurs to communicate tacit knowledge (Carayannis and Campbell 2014). This resulted in co-creation, as noted in some of the cases of our samples. Firms assessed product and service feasibility and efficacy which enabled them to decide whether to consider the venture idea or pivot them.

In line with previous literature, our analysis suggests that firms and entrepreneurs who are open and transparent on their purpose and true to the efficacy of their offerings to the stakeholders can increase trust among stakeholders (Asveld, Ganzevles, and Osseweijer 2015) and likelihood of adoption of their offerings (Kuester, Konya-Baumbach, and Schuhmacher 2018). Thus, they can advance feasibility belief about their ventures and self-efficacy belief in venture creation and firm development. Moreover, firms and entrepreneurs who listen and take it seriously about stakeholders' and users' actual needs, values, expectations and concerns can develop dynamic capability (Teece, Pisano, and Shuen 1997). They modify their products and service design to accommodate users' and stakeholders' needs and expectations, thus making optimal desirable solutions which are sustainable and responsible (Owen et al. 2013; von Schomberg 2013). Firms and entrepreneurs who are responsive towards stakeholders and users can increase their social reputation (Zahra and Wright 2016). Thus, firms can boost their venture feasibility and efficacy belief, hence OC in venture creation and firm development.

Including a diversity of stakeholders and users early in the venture creation and development enables firms to develop venture feasibility through knowledge diversity, resources and collaboration opportunities. Similarly, anticipation enables subjective judgement on firms' and entrepreneurs' self-efficacy and venture efficacy. Finally, reflexivity and responsiveness enhance venture feasibility and efficacy beliefs, ultimately advancing firms' and entrepreneurs' OC. Moreover, our analysis shows that practising RI in venture creation and firm development empowers users and stakeholders (Brand and Blok 2019; Iakovleva, Oftedal, and Bessant 2019a). Such initiatives also increase stakeholders' confidence about the efficacy of the offerings, who can recommend the solutions to others resulting in ripple effects.

Conclusion

We sought to explore the extent to which RI dimensions of inclusion, anticipation, reflexivity and responsiveness contribute to building OC in venture creation and firm development. The motivation was that despite the growing interest in RI in recent years, its

application in the business context remains limited. Accordingly, we argued that firms and entrepreneurs could incorporate the RI principal dimensions in innovation and entrepreneurial activities to ensure their ventures are responsible and sustainable, which helps build OC critical for reducing the risk of failure.

The findings reveal that although the firms and entrepreneurs have not integrated RI in innovation and entrepreneurship per se, they practice RI in varying degrees in venture creation and firm development activities. The findings also reveal that the dimensions of RI principles: inclusion, anticipation, reflexivity and responsiveness enabled firms and entrepreneurs to make a subjective judgement about the feasibility and efficacy of innovative products and services. Specifically, RI helped them judge the socioeconomic, socio-ecological and socio-ethical feasibility and efficacy of innovative ideas and decide whether or not to consider such ideas for venture creation and firm development. Thus, it enabled them to build OC in venture creation and firm development activities, thus reducing the risk of failure. Early start-ups and entrepreneurs, however, find adopting and practising RI principles challenging due to resource constraints and fear of losing opportunities to competitors, despite their willingness to do so. Nonetheless, those who could incorporate the RI dimensions in their innovation and entrepreneurial activities were more confident about their venture success.

In line with previous debates, the findings allow us to argue that the RI framework facilitates start-ups and incumbent firms to identify, understand, and critically evaluate the potential social benefits and hazards of innovation and entrepreneurial activities (Markus and Mentzer 2014; Zahra and Wright 2016). They can build OC in venture creation and firm development, thus increasing firm and entrepreneurial success (Scholten and Van Der Duin 2015; Brand and Blok 2019). Moreover, the RI framework plays an instrumental role in interacting with socioeconomic, socio-ethical, and socioecological factors (Long and Blok 2018; Lubberink et al. 2019; Wickson and Carew 2014; Voegtlin et al. 2022) critical to building OC in venture creation and firm development (Gemmell, Boland, and Kolb 2012).

Our study adds to this ongoing debate about RI in the industry by providing empirical evidence of the RI approach to building OC for entrepreneurial ventures, bridging the RI and entrepreneurial literature. Further, the findings indicate real practical benefits and encourage entrepreneurs and firms to leverage RI in their venture creation process. They also point out the need to relook at policies aimed at supporting entrepreneurs and firms. Engaging potential users, the public, funding bodies, insurance companies, healthcare professionals, and policymakers early on ensured access to funding, facilitated collaboration and enabled OC to carry out the potential venture creation process in the health and welfare sector.

However, entrepreneurial firms often need more mechanisms, time, and resources to engage stakeholders. Policy initiatives are needed to facilitate the RI approach in business to make them more affordable and available. Such policies include creating boundary innovation spaces such as living labs, social labs, and accelerators where firms will get support in finding and engaging with different stakeholders. Besides, funding initiatives supporting deliberate stakeholder inclusion in the firm innovation process might be helpful. Lack of knowledge about responsible innovation and its underlying dimensions and the value of practising them could also be overcome by providing training and help in building structured engagement processes.

While the above holds, this research is not without limitations. Although it allows studying firm practices, it is limited to the same region and industry, limiting its geographic and industry diversity. Future studies should consider RI practices in other contexts and regions. Although all the firms in our research have managed to achieve some measure of OC through RI, firms still perceive RI to be difficult to implement in business activities. Therefore, some of their behaviours may not represent the best RI practices. Moreover, most case firms have not yet scaled up their products/ services, and hence the effects of practising the RI approach on firms' market success or innovation diffusion is beyond the scope of the present study. Hence future research should focus on longitudinal design to explore the effects of the RI approach in the industry.

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Paper IV

8. Responsible research and innovation: innovation initiatives for positive social impact

Raj Kumar Thapa and Tatiana Iakovleva

8.1 INTRODUCTION

> We believe that if we can create value to the society at large, and do our job well, satisfactory economic results will follow and allow us to build a stronger company with time.
>
> Åsmund S. Laerdal

Business organizations invest in innovation for the purpose of competitive advantage from corporate profitability and organizational growth perspectives. The primary focus of these organizations is in shareholders' value maximization, which requires business growth and quick turnover. Due to the growth imperatives and growing competition, the organizations are in constant pressure to invest in research and innovation for faster outputs (Christensen and Raynor, 2003).

Over the past five decades, business organizations have made substantial contributions in economic development and human wellbeing with innovation (Fagerberg, Fosaas and Sapprasert, 2012; Martin, 2012). However, with innovation and business activities, a number of societal, ethical and environmental issues have also been summoned in the course of development (Martin, 2016).

Despite the adoption of corporative social responsibility as their strategic management since quite a long-time, larger corporations are being criticized for not contributing enough to social and environmental reconstruction (Lazonick, 2014). Furthermore, due to the dominant shareholder value maximization ideology, these corporations are mainly concentrated in value extraction rather than value creation as per the interest of shareholders (Lazonick, Mazzucato and Tulum, 2013; Lazonick 2014). Such attitudes and practices have actually widened the societal and environmental problems.

These incentives of business raises the responsibility issues of the businesses, and raises the public concerns about the purpose and underlying motivations behind their business innovation (Owen et al., 2012).

Innovations which fail to address public concern and reflect on the underlying purpose, could meet public resistance (Asveld, Ganzevles and Osseweijer, 2015). Such innovations, though, possess the potential of addressing societal problems, and could potentially be responsible products, but would not be accepted by the users. Aligning with this line of argument, it is therefore necessary for the organizations to reflect on the purpose, process and outcomes of the innovation projects (Owen, Bessant and Heintz, 2013; Stahl et al., 2017). Such innovation outcomes could find diffusion to scale alleviating societal and environmental problems, thus increasing positive social impact.

With an explorative case study of a business organization within the medical industry, this chapter aims at answering the research question 'How do business organizations pursue responsible innovation in business development and create positive social impact?'

In the sections that follow, we present Responsible Research and Innovation (RRI), and social impact in section 8.2, followed by the research approach and details of the case company in section 8.3. In section 8.4, we present our findings followed by discussion and conclusion in section 8.5.

8.2 RRI AND SOCIAL IMPACT

Innovation is considered as a mechanism for competitive advantage to expand economic horizons (e.g., Teece, Pisano and Shuen, 1997). Business organizations are therefore concentrated on innovation outputs rather than innovation outcomes and the social impact of such innovations in society (Martin, 2016). Innovation has transformed the society and wellbeing. However, in many occasions, it is being exploited by certain interest groups at the cost of the rest of society and the environment. The growing economic disparity, environmental and ecological degradation are some of the alarming issues of recent times. Such issues raise public concern about the fundamental purpose, product, and outcomes and overall underlying motivations of such innovation (Stilgoe, Owen and Macnaghten, 2013; Stahl et al., 2017). This necessitates the focus of innovativeness of businesses which should be on innovation outcomes for broader social impacts rather than outputs as a means of competitiveness for economic growth.

'Social impacts include all social and cultural consequences to human populations of any public or private actions that alter the ways in which people live, work, play, relate to one another, organize to meet their needs, and generally cope as members of society' (Burdge and Vanclay, 1995, p. 59). Social impact

of innovation therefore could be described as any change that particular innovation brings in the environment and society.

The principle aspect of RRI is responsible process for responsible innovation outcomes (Owen, Bessant and Heintz, 2013). This implies that business innovation depends not only on the novelty of the product or services that an organization offers to the customers, but also on how they produce and deliver, and what the potential impact of such a product or service could be on society at large.

This also implies that innovations targeted at alleviating societal and environmental problems are diffused to a scale thus benefiting larger communities by creating a positive social impact. The focus of businesses should therefore be on *purpose*, *process* and *outcomes* of their research and innovation activities, as suggested by Stahl et al., 2017 in their maturity RRI model.

8.2.1 Purpose

The purpose of a research and innovation project must be clearly specified. Organizations can reflect on the purpose of their research and innovation project, for instance through a mission statement. The purposed statement reflects the interest and motivation for a particular research and innovation project. In order to cast a positive social impact, the value creation through research and innovation should be aligned with the norms, values and legal status of society. The purpose of such research and innovation should be emphasized, based on the need of society, for instance alleviating societal problems keeping in mind to align the innovation activities as per the expectations of society and not just avoiding harm. The purpose should be focused mainly on societal desirable innovation process targeting at responsible outcomes.

8.2.2 Process

The process is about reflection on action. What are the necessary actions organizations should perform in order to align with their purpose of research and innovation? Who are included in the research and innovation activities and for what purpose? For example, inclusion of users and the public will bring diverse knowledge in the innovation process. In many occasions users have solutions to the problem, while on other occasions they have the solution but may not have the know-how to realize the product. Further, on some occasions they need to be educated, made familiar and even empowered. It is important to define clear outcomes while engaging stakeholders into innovation process. This represents responsible thinking and responsible acting by the organizations, which helps them to add social impact.

8.2.3 Outcomes

The outcomes of research and innovation cannot be confirmed at the beginning of the process. In some occasions, though the purpose and motivation of innovation is for responsible outcomes and the responsible processes are followed strictly, the outcomes may result in causing negative externalities in society and the environment. In such a situation, the essential act is to respond to such consequences immediately and avoid causing further damage. It is to be acknowledged that RRI processes will not necessarily bring responsible outcomes, but help develop a culture of reflecting and responding to take care and protect the society and environment from further damage. The aspiration of RRI can be achieved only if an organization demonstrate responsiveness, meaning either abandoning manufacturing a product which adds negative externalities in society and the environment or take it back to discussion for modification or an alternative solution. Such acts enhance reflexivity of the organization and demonstrate how serious they are about taking care of the environment and society. This could enhance trustworthiness of the business organizations in society, which could affect reputation and brand image.

Innovation needs to be diffused to scale in order to benefit larger communities and scale up the positive social impact in society. Innovation cannot be considered responsible until and unless it brings positive change in the society (von Schomberg, 2013).

Scaling up can be done through depth and breadth. Scaling depth here means to spread responsible innovation deep into the community at local and national levels, while scaling breadth means spreading responsible innovation out of the national boundary so that the global community can access such an innovation in alleviating their local or regional problems.

8.3 RESEARCH APPROACH

In the current study, we adopted a single case study method (Yin, 2003) of a Norwegian company operating in the health industry. Data collection involved in-depth interviews performed by the authors with a technical director associated to Laerdal Emergency Care, a project manager of Laerdal Medical and the director of educational strategy and standards in partner company 'SAFER' (Stavanger Acute Medicine Foundation for Education and Research). In addition, we used observations (visits to the production facilities of Laerdal Medical) and secondary material available in the public domain, including the Laerdal Report on Sustainability (2016), the Laerdal Impact Report (2018), the Laerdal website (Laerdal, 2018) and a book about Laerdal, *Saving More Lives Together – Vision for 2020* by Nina Tjomsland (2015). Besides these, two student reports devoted to innovation processes in Laerdal,

based on three interviews performed in 2018 (recorded and transcribed) with the supervision of authors are also included as additional materials.

8.3.1 The Case Company

Laerdal AS was founded back in 1940 by Aasmund S. Laerdal, in Stavanger, a small city in Norway. Inspired to bring joy for local kids, his business venture was focused on commissioning and publishing books and manufacturing wooden toys for kids. From the beginning of the establishment, the focus of the company was in constant product development. For this purpose, Aasmund shared his visions with the employees, and he searched out the profession- als and experts who could assist and advise him. He invested in education, explored different nations and cultures, and brought back knowledge, which could assist him to achieve his vision and sought out new opportunities. Back in 1949, he came to know the use of soft plastic in manufacturing toys for kids. With constant passion, determination, dedication and experimentation, he finally achieved success in manufacturing his first toy, Anne, from soft plastic in 1950 and his company became the first to manufacture dolls out of soft plastics in the European region. This expertise was later extended in manufacturing the popular Tomte toy cars. The company saw an opportunity for mass production and export to low-cost countries and was able to export toys to over 110 countries.

From kids' toys to life saving

Since the establishment of the enterprise, Aasmund was constantly thinking about a new product development, a product that was suited for production in Stavanger. Being an expert in soft plastic in Norway, Laerdal was approached by Civil Defence in 1953 and asked to develop imitation wounds for training. This brought an opportunity for Laerdal to extend its network into the medical profession. With its expertise in manufacturing dolls and cars out of soft plastics, and collaborating with the physicians and experienced surgeons, it was able to create accurate models of relevant wounds. Furthermore, Laerdal was able to produce a glue to fasten the wounds on the skin without hurting while subsequently removing it after constantly testing different types of glue.

In 1954, a personal incident happened with the firm founder. Aasmund found his two-year-old son floating unconscious in the sea. He immediately took the inert body of his son out of water, slapped and shook him to clear his airways, and stimulated him to breathe, thus saving him. This emotional incident laid the foundation for the company's next major focus area.

With the extended networks with health specialists, Aasmund came to know that there had been substantial development in a new and much better method

of resuscitation, involving mouth-to-mouth breathing by a group of physicians and engineers in Baltimore.

The emotional incident that Aasmund experienced while saving his own son and the new development within resuscitation inspired him to enter into the manikin manufacturing business. Making manikins was difficult, but the more difficult part was how to overcome psychological and cultural resistance among people to make them acceptable to use. Beside these issues, price and quality of the product should not be ignored in order to make many people benefit from such innovation. In close collaboration with anaesthetists in Stavanger, Aasmund was successful in prototyping his first manikin, 'Resusci Anne' in 1960 and he demonstrated it to American resuscitation pioneers in New York. This event resulted in friendship and the collaboration of Aasmund with one of the resuscitation pioneers, Peter Safer, who suggested the inclusion of a chest ring for compression training, which Laerdal Medical company complied with. The still looming challenge at that moment was about inspiring as many people to learn and implement the mouth-to-mouth technique to help save lives.

Being a strong advocate of resuscitation, an anaesthesiologist Bjorn Lind, played an essential role in bringing his colleagues to join forces to convince people of the importance of mass training in resuscitation. The first and major breakthrough occurred when a group of banks donated 650 manikins to primary schools where both teachers and students were empowered in using manikins. Dr Lind followed the training and noticed that children learned resuscitation well, like their teachers (Lind, 1961). Furthermore, the outcomes of such intervention were scientifically recorded, analysed and made available (Lind and Stovner, 1963). Laerdal Medical was then able to attract interna- tional attention, and Norway emerged as a pioneering nation in the history of life-supporting first aid and became a role model in conveying the message to the world that every schoolchild can learn how to save a life.

Aasmund's obsession of helping save more lives intensified in the search for more opportunities. The company was proactively involved in healthcare innovation. In August 1961, in close cooperation with Dr Safer and German specialists, Laerdal Medical initiated and hosted the First International Symposium on Emergency Resuscitation in Stavanger, which was attended by specialists from all over the world.

The establishment of a Cardio-Pulmonary Resuscitation (CPR) committee by the World Federation of Anaesthesiologists in 1964 and a discovery that conveyed that external chest compressions could provide a circulation of blood to the brain when the heart stopped beating, and increase greatly the possibility of revival, proved to be crucial potential for the Laerdal company. As a result, in 1969, Laerdal Medical produced Resusci Anne for CPR, capable of being used to practice artificial ventilation and external chest compressions. In addi-

tion to this, a series of other products associated with first aid were produced and Resusci Baby was one of them. The same year was marked with the introduction of the Resusci Folding Bag, Pocket Mask to protect the rescuer and Vacuum Mattress to protect the patient, followed by a disaster kit.

In 1971, Laerdal Medical introduced Resusci Anne, equipped with a printer giving feedback to the trainee and at the same time providing important information about the efficiency of the training and possible areas of improvement in the manikin.

Following the recommendation of the American Heart Association (AHA), Laerdal Medical introduced teaching of CPR to lay persons in 1973 and that proved to be the big step in empowering lay people to help save more lives. To promote teaching of CPR, Laerdal Medical printed informational material for the medical sector in 15 different languages.

In 1978, Laerdal Medical decided to concentrate fully on saving lives and stopped producing toys for children. In the same year, Aasmund received an International Award of the AHA and became the first non-physician to receive such award. The same year he became an honorary member of both the British Association for Immediate Care and the Norwegian Society of Anaesthesiologists. He was also honoured by the University of Pittsburgh.

By 1979, Laerdal Medical was the established market leader exporting abroad 95 per cent of the outputs from several production lines. The Laerdal company decided to channel some of the profits into a new foundation, hence in 1980 the Laerdal Foundation for Acute Medicine was established in collaboration with the University of Oslo. The foundation carries out research projects and educational initiatives.

The responsibility of running the company transferred to Tore Laerdal, after the death of his father Aasmund in 1981. Since then, innovation for broader impact has become Laerdal's culture. In addition to this, Laerdal is actively involved in any innovation activities in association with helping to save lives. In 1982, the Laerdal Foundation helped initiate and support an international conference for CPR trainers in London together with the AHA. During the 1980s, Laerdal collaborated on two projects for mass CPR training in the Stavanger region under the motto 'Action Rogaland 1983: You can save lives'. This initiative resulted in 5,000 volunteer learners over just two weekends.

Inspired by such impressive outcomes, Stig Holmberg from Gothenburg developed a Swedish CPR training model to train all healthcare personnel. Laerdal contributed to the training programme and also sponsored thousands of posters to hospitals and health institutions. The posters were designed by Laerdal and were simple to understand and easy to learn from.

Since the early 1990s, posters for both basic and advanced life support were printed in many languages for European Resuscitation Council and were displayed in thousands of hospital emergency rooms and training sites.

Beside these supportive activities, Laerdal constantly focused on innovation for product efficiency advancement for better outcomes and impacts. In 1999, with close collaboration with physicians, Laerdal developed SimMan, an advanced patient simulator. The development of SimMan was to help the extensive training of health personnel in US hospitals in order to reduce an estimated 50,000-100,000 of unnecessary deaths each year due to errors made in those hospitals.

In the same year, Laerdal bought Medical Plastics Laboratory Inc. (MPL) in Gatesville, Texas and introduced the SimMan project (Tjomsland, 2015). MPL is now called Laerdal Medical Texas where SimMan is the major production. Since its entry into the medical industry, Laerdal Medical developed a broad range of products and programmes to support resuscitation training and emergency interventions. With a focus on increased patient safety, in 2000, Laerdal Medical broke ground in the field of medical simulation with the introduction of relatively low-cost patient simulators, allowing for risk-free interactive training in emergency care.

Laerdal was aware that helping to save lives is not possible all alone despite a continuous focus of development and innovation. It continuously searched for collaborators and partners with whom values, expectations and purpose could be aligned with its core mission of helping to save more lives. In addition, Laerdal constantly looked for opportunities to acquire the companies associated with its core mission. In 2002, Laerdal collaborated with a Danish-based company, Sophus Medical to further explore interactive medical training products. In 2003, Laerdal acquired Sophus Medical, which is now called Laerdal Medical Sophus and is leading in the field of micro simulation training.

During 2004, Laerdal was able to launch extensive products covering educational micro simulation programmes for pre-hospital, in-hospital and military segments. In the same year, Laerdal officially opened a new factory in China which enabled it to provide a quality facility in the East Asian region. Similarly, it opened a factory in Monterrey, Mexico, in 2006.

In 2006, Laerdal's attention was drawn towards maternal, newborns and child health. It is highly acknowledged by the American Academy of Paediatrics (AAP) that the heart of simulation lies neither with the simulator nor the technology, rather with the educational methodology. Laerdal partnered with AAP to advance educational science and resources necessary for training in neonatal resuscitation.

Simulation-based training in neonatal resuscitation programmes was being used in 120 countries and was in high demand. However, it was complex and resource-demanding to implement such programmes in low-resource countries. Unfortunately, the need for such programmes is high in those low-resource countries where many children and mothers lose their lives during birth

due to lack of birth-related education and training. Laerdal was looking for ways to address such challenges in low-resource countries. As a result, in 2010, a daughter company, Laerdal Global Health (LGH) was established as a not-for-profit company in order to develop high-impact, low-cost training and therapy products aimed at helping save the lives of newborns and mothers in low-resource countries.

Today, Laerdal is a global company with more than 1,500 employees in 24 countries, dedicated to helping save lives through resuscitation, emergency care, and patient safety.

With its own expertise and existing networks and collaborations, the company targets at scaling its social impact globally by helping save more lives through constant improvement and innovation.

8.4 FINDINGS

8.4.1 Purpose

The Laerdal company is driven by its mission of helping save lives. 'Help save half million additional lives every year by 2020' is the new goal that the Laerdal company announced on their web-page and in strategy documents. This ambitious goal underscores the need for focusing the activities and organizational capabilities on areas where Laerdal believes it can make the biggest impact. With a long experience and expertise within resuscitation research, patient safety, and global health initiatives, Laerdal is confident in achieving its goal. The company's mission statement of helping to save more lives reflects the purpose of organization, research, and innovation that the company carries out and supports. Though profit is essential for scaling up innovation capabilities in order to scale up social impact, it is not the top priority of the company.

8.4.2 Process

In order to achieve the ambitious goal and scale up social impact, Laerdal is continuously engaged in innovation aligned with its core mission, helping save more lives. For Laerdal, innovation is not about the bare novelty of technologies or products but it is about its contribution to helping save lives. This implies innovation in Laerdal is about impact, and innovation can only have enormous impact if it is diffused to scale. This requires the detailed understanding of needs and expectations of end users.

As expressed by the founder, Aasmund Laerdal, "sustainable business is only possible through developing [the] ability to listen, endless curiosity, practical problem solving, respect for [the] customer, hard work and a passion

for continuous improvement" (Tjomsland, 2015, p. 16). This has translated into an organizational culture within Laerdal. Meeting customers' and users' needs and expectations requires their inclusion at the very early stage of the innovation process. Laerdal articulates its sales forces located around the globe to include the users and customers' voices and ensures their voices are heard in the innovation process.

> We gather constant customers and users feedback about our product and services through our sales forces located all over the world and constantly try to respond to the feedback and their expectations whenever and wherever possible. *Technical director*

Achieving ambitious goals and attaining sustainable business growth is not possible without reliable collaboration, partnerships and networks. Laerdal has succeeded in collaborating with a number of complementary organizations that can build and implement solutions for end users. At the same time, it is constantly seeking to extend networks with reliable partners with common goals and shared values. The company believes that future success can only be realized through strong commitment to global partnerships, cooperation, and constantly striving to further develop alliances and partnership in many countries. Establishing strong and sustainable cooperation requires constant demonstration of reflexivity and responsiveness on actions and commitments. Through its responsible attitude and actions, Laerdal is able to bring many strategic partners on board within its network to support its mission of helping save more lives.

As of today the Company collaborates with The American Heart Association (AHA), the American Academy of Pediatrics (AAP), HealthStream, the National League for Nursing (NLN), Philips Healthcare, SAFER (Stavanger Acute medicine Foundation for Education and Research) and Jhpiego. With close collaboration and alliances with these strategic partners, Laerdal is able to innovate quality products and services in order to enhance helping save more lives. These collaborations actually formed a platform for constantly learning for better innovation outcomes and even co-creating innovative solutions, for instance, Laerdal collaborates with AHA on several large-scale projects such as CPR, a CPR in schools programme, Heartcode eSimulation courses and Resuscitation Quality Improvement Programme (RQI) being able to revolutionize resuscitation. With close collaboration with APP, Laerdal co-created several simulators supporting the Newborn Resuscitation Programme (SimBaby, SimNewB, and Premature Anne), e-learning programmes, and the suite of Helping Babies Survive educational modules. Laerdal's collaborators are also customers and users of the majority of the Laerdal products. Working closely with them therefore enabled Laerdal to understand actual needs and

expectations. To meet their expectations and establish strong relationships, the company focused on innovation management from the design stage onwards.

> We prototype many different products and test them with customers and users. If one fails, the other would work. If all fail, we redo it with feedbacks from customers, users and the experts until we get satisfactory outcomes. *Project manager*

> Keeping customers' and users' satisfaction high to build sustainable relationships is what Laerdal believes. Responding to the constructive feedback of the users and customers is to demonstrate respect and proof that their voices are heard and respected.

> Some of our customers did not like colour of the manikins and asked us to change it to represent different races. Though it is costly and difficult procedures for us, we do respect their cultural expectations and changed as per their suggestions. *Project manager*

Networking with external partners is also forming a platform for inclusion of diversity of knowledge and expertise, which in fact enables Laerdal to understand the desirability and acceptability of innovation in different contexts. Including Jhpiego, a non-profit health organization affiliated with the Johns Hopkins University, Laerdal is able to successfully implement the Helping Mothers Survive Programmes in low-resource countries.

In order to focus on need-based research and innovation to achieve its ambition, Laerdal company keeps itself updated with the most recent research associated with healthcare. Besides its own research centre, Laerdal contributes to research through donations to the Laerdal Foundation for Acute Medicine and support to the SAFER simulation centre.

8.4.3 Outcomes

Innovation outcomes are uncertain. However, adequate consultation with users, customers, stakeholders, experts and other relevant actors at the beginning of the innovation process could lead to better outcomes. In addition to responding to the feedback from the stakeholders, customers, users, and partners, they need to keep room for constant improvement of the product and services for better productivity. In other words, the probability of achieving expected innovation outcomes is higher when innovation activities are aligned with purpose.

The revolution on resuscitation, emergency care, and helping babies survive and helping mothers survive is only possible through responsible innovation outcomes that Laerdal has adopted and implemented. For instance, the e-learning programme and initiatives such as Resuscitation Quality Improvement (RQI) are innovation outcome that have optimized the way

CPR training is delivered. Simulation training and related activities can be considered as another responsible innovation outcome, which contributes in the reduction of deaths due to medical errors.

8.4.4 Innovation Diffusion – Scaling Depth/Breadth

As the historical development of the company illustrates, Laerdal Medical was quite successful in offering its product and services within treatment of sudden cardiac arrest and emergency care in high-resource countries. The company has a broad international market, offering its products and services in 24 countries. Since 2010, via LGH, the company has extended its services in low-resource countries in Asia and Africa in order to help save lives of newborns and mothers, preventing deaths due to birth-related complications. In one particular hospital, over the period of six months, the application of Laerdal training through the instalment of modern baby manikins combined with a digital self-assessment training programme, resulted in reducing the baby death rate by 40 per cent. It can be concluded that the company is con- stantly scaling up innovations both in terms of depth as well as breadth.

At the same time the company is conscious with regard to how and where to grow its business. Aligning its growth ambitions with its mission of saving lives lies in the core of the growth strategy for Laerdal. The company is trying to achieve growth through building networks, alliances and partnerships with trusted partners to achieve higher social impact.

> We cannot grow as we want because we need to concentrate on our capacity, quality and maintain our image at the same level as we have been able to so far. Focus on growing faster would be problematic for maintenance of organizational culture and overall performances. The only thing we could do is to find the right partner and build alliances. *Technical director*

We summarize the major RRI elements, such as purpose, process, outcomes as well as scaling and social impact for Laerdal company in Table 8.1.

The company can scale up positive social impact, further increasing its RRI approach by covering resuscitation and emergency care services in low-resource countries. For this, there should be local and national govern- ment initiatives and healthcare policies need to be considered, and this clearly signifies the need for inclusion of relevant stakeholders and actors from respective societies.

Table 8.1 RRI approach and social impact

Purpose	Process	Outcomes	Scaling	Social Impact
Stated clearly in mission statement: Help save more lives (saving lives through quality and accessible healthcare facilities)	Research and innovation aligned with the core aspects of RRI (inclusive decision in research and innovation activities) Production of training and educating materials (need-based innovation)	Quality products (increased efficiencies as per the expectations of customers and users) Empowering users and local community for quality healthcare Educating and empowering school kids in quality CPR, providing kits necessary for it	Production sites extended in global scales Introduction of new business unit and innovative approach to subsidize costs for low-resource countries Extending programmes to support helping save more lives mission	Saved more lives (reduced death due to sudden cardiac arrest and deaths due to medical errors in high-resourced nations) Saved lives of newborns and mothers in low-resource nations (reduced death of newborns and mothers due to birth-related complications) Extended affordable care services in low-resource nations in Africa and Asia

8.5 DISCUSSION AND CONCLUSION

Drawing on the case study of the Laerdal company, this chapter has presented how socially responsible attitudes and activities of organizations during business innovation can actually boost positive social impact and sustainable business growth.

As a known proverb says: ‘Necessity is the mother of invention’. Demand-based innovation or user innovation developed with broader inclu- sion of stakeholders and lay people are more compatible and bear higher probabilities of innovation diffusion to scale. Furthermore, such bottom-up innovation initiatives not only facilitate the development of innovations, but also contribute to social empowerment (von Hippel, 2005, 2017). However, inclusion of stakeholders, users, and the public in the early stage of innovation activities as per the aspirations of RRI appears to be a costly, time consuming and complicated process. Such approaches can easily be presumed to result in delayed decision-making or the state of no decision at all. Such perspectives

prioritize monetary interests over and above the interest of the stakeholders, customers and society, which would not be beneficial for businesses in the long run. In fact, underestimation of the role of such societal actors would be too costly for the companies. Inclusion of more people, especially user groups at the very beginning of the innovation process, gives deep insights into better solution designs and responsible innovation outcomes. Such inclusive and responsible aspects have enabled Laerdal to be the world leader in resuscitation and medical simulation. A socially responsible purpose and organizational commitment are the major factors behind Laerdal's success.

Stating an ambitious, purposeful and impressive mission statement does not itself reflect responsible behaviour of a company. Such an impression will be illusive if the company fails to translate the statement into actions. This is also associated with companies' trustworthiness and reputation in society, which will ultimately determine the survival and growth of the business. Socially responsible business, in the long run, can be profitable by being responsible. This line of our argument is aligned with the case of Laerdal, which is able to extend its mission of helping save more lives to the next level, aiming at helping save 500,000 more lives every year by 2020 (Laerdal Report on Sustainability, 2016), extending its positive social impact in society. We therefore argue that business innovation aligned with RRI aspirations would enable to address social problems with the help of research and innovation activities. Such initiatives from business communities mean sustainable business and positive social impacts of their business innovation to society.

Innovation that incorporates public concerns about the purpose and motivation of innovation would get a green signal from society for desirability and acceptability to a larger extent, since such innovations are designed and developed for society, with society (Owen, Macnaghten and Stilgoe, 2012). Furthermore, such innovations carried out with broader inclusiveness, representing public concerns, values and expectations would result in diffusion to scale, which is necessary for creating and extending social impact. Being able to cast positive social impact in society, facilitates building trust among the stakeholders and the public. This is how organizations can build brand image and get continuous support from society. This in fact adds a moral obligation of organizations to maintain their image in the public domain and opens up growth opportunities to spread positive social impact further. This, in turn, extends the level of social responsibility of businesses, an obligation of taking care of society and the environment, a culture of responsible business innovation.

Our line of argument here is responsible innovation, activities aligned with purpose, process and outcomes would result in socially acceptable or even desirable innovation outcomes. Such innovations are compatible and achieves diffusion to scale creating social, environmental and economic

values. However, how to ascertain that responsible acts leads to responsible outcomes remains ambiguous. Social impact assessments with respect to RRI could be one possibility to evaluate how far companies are able to extend positive social impact through business innovation activities.

Based on analysis of our case firm, its research and innovation process, purpose and outcomes and literature we therefore suggest the following Social Impact Assessment framework (SIAF), depicted in Figure 8.1.

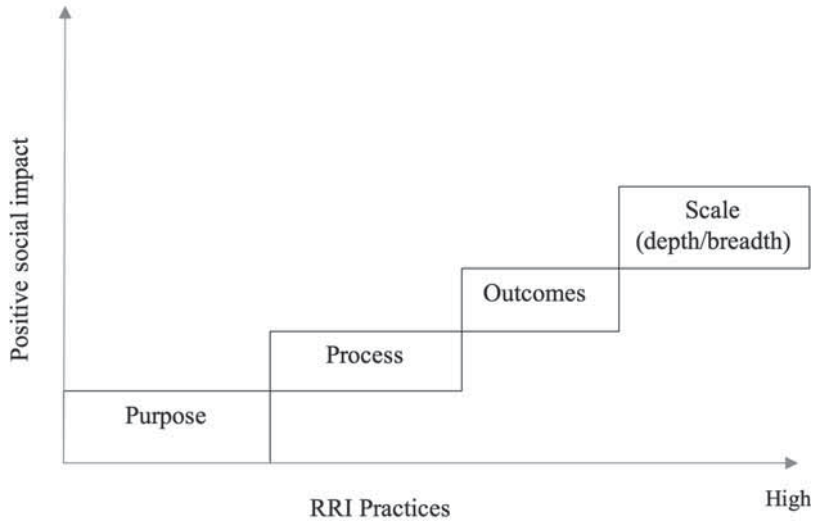

Figure 8.1 RRI and social impact

Social impact assessment frameworks (SIAF) can actually enable businesses to perform self-assessment of their own research and innovation projects and to evaluate the socioeconomic and environmental impact of such projects. The SIAF will not only find application in assessing responsible innovation activities within the organization but also facilitate organizations to build their reputation and sustainable growth opportunities. What we have demonstrated through this study is that prioritizing societal interest over mere profitability would actually result in both profitability and sustainable growth in the long run and this is associated with the socially responsible purpose and outcomes of business innovation. However, profitability of business should not be overlooked. Profitability is essential for research and innovation of products or services and supplying for broader communities for exponential positive social impact. We therefore emphasize the necessity for businesses to align with purpose, process and innovation outcomes.

RRI thinking and practices in research and innovation would enable businesses to identify and prioritize the most relevant innovation necessary for societal advancement. Such practices help in initiating innovation culture to focus need-based innovation and innovation aligned with the interest, value and legal status of society and keep aware of not adding negative externalities which could mean the cause of social and environment destruction. RRI practices would enable all societal actors to change their mindset and enable them to take care of society and the environment, or at least demotivate them from performing any actions, which could destabilize society and the environment. Any initiative to take care of the environment and society would definitely leave a good message in society and cast a positive social impact.

However, a responsible process, product and responsible outcomes by themselves would not necessarily cast sustainable positive social impact unless responsible innovation is fully diffused in society for broader social reformation. This implies the necessity of scaling up such innovation to serve a global community. Alleviating local, regional or national problems does not necessarily represent eradication of the problem, since a problem in any part of the world be the cause of problem for the local community in the present context of globalization. Scaling up of positive social impact is only possible if an organization could scale up responsible innovation both locally as well as globally; scaling up in terms of depth and breadth. The underlying aspect of RRI is to orchestrate research and innovation activities necessary for maximizing positive innovation outcomes for positive social impact and not just on research and innovation activities to avoid harm.

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