Responsible Innovation & Entrepreneurship – The Role of Stakeholders & Uncertainty in Disruptive Technology Development

by Karsten Bolz

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Submitted by Dipl.-Wirtsch.-Ing. **Karsten Bolz**

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1st Supervisor:	Prof. Dr. Christine K. Volkmann Chair of Entrepreneurship and Economic Development & UNESCO-Chair of Entrepreneurship and Intercultural Management Schumpeter School of Business and Economics University of Wuppertal
2nd Supervisor:	Prof. Dr. Peter Witt Chair of Technology and Innovation Management Schumpeter School of Business and Economics University of Wuppertal

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ABSTRACT

This dissertation is located at the intersection of stakeholder theory, entrepreneurship and innovation research and demonstrates that the concept of Responsible Innovation (RI), with its premise of early stakeholder engagement in innovation processes, is of immense relevance to entrepreneurial organizations, especially with regard to uncertainties in disruptive technology development.

Part 1 of this dissertation pioneers the connection of RI to entrepreneurship research. The differing interpretations of RI and three core aspects are explored: design innovation, normative ends and collaborative reflection. After laying out this RI scheme, the notion of entrepreneurship is examined in light of this construct. Furthermore, operationalization strategies of RI in entrepreneurial organizations are outlined on a conceptual level and in practice, with a focus on stakeholder engagement as the key element. Moreover, the vital role played by stakeholders in entrepreneurial organizations and their influence on uncertainties of innovation processes are indicated.

In Part 2 of this dissertation, this role of stakeholders is scrutinized more closely. It identifies the reduction of uncertainties as a core driver of stakeholder engagement activities. A mixed-methods approach was utilized. In the qualitative study, nine in-depth interviews were conducted and analyzed. A structure equation model approach was adopted for the quantitative study; 119 questionnaires were completed by managers in the field of advanced biotechnology. Part 2 evidences the vital role of stakeholder engagement in terms of reducing technological, commercial, social and organizational uncertainty during innovation processes in disruptive technology development.

TABLE OF CONTENTS

Acknowledgements III

Abstract V

Table of Contents VI

List of Figures IX

List of Tables X

List of Abbreviations XI

1 Introduction 1

1.1 Background, Relevance and Research Gap 1

1.2 Research Aim and Questions 5

1.3 Structure of the Dissertation 6

Part 1 10

2 The RI - Entrepreneurship Nexus 10

2.1 The RI Concept 10

2.2 Relations between RI and Entrepreneurship 12

2.2.1 Design Innovation 14

2.2.2 Normative Ends 16

2.2.3 Collaborative Reflection 19

2.3 An RI-Entrepreneurship Framework 22

2.3.1 The Role of Stakeholders within the Framework 23

2.3.2 The Process Dimension of the Framework 24

2.3.3 Examples of the RI–Entrepreneurship Nexus 28

2.4 Discussion 29

3 RI and Disruptive Technology Development – Insights from the Debate on Advanced Biotechnology 36

3.1 Providing Space for Collaborative Reflection – A Workshop Approach 37
3.2 Entrepreneurial Perspectives on the Operationalization of RI in the Advanced Biotechnology Field 38
3.3 Discussion 41
Part 2 44
4 The Role of Stakeholders in Disruptive Technology Development Processes 44
4.1 Theoretical Background 45
4.1.1 RI and Stakeholder Management 45
4.1.2 Stakeholder Management and Disruptive Technology Development 49
4.1.3 Innovation and Uncertainty 50
4.2 Research Approach 53
4.3 Findings and Discussion 56
4.4 Discussion 60
5 The Influence of Stakeholder Engagement on Uncertainty – A Structure Equation Model Approach 70
5.1 Uncertainties of Innovation Processes 71
5.1.1 Technological Uncertainty 71
5.1.2 Commercial Uncertainty 72
5.1.3 Social Uncertainty 73
5.1.4 Organizational Uncertainty 74
5.2 Knowledge Transfer 75
5.3 Hypotheses 76
5.4 Research Design 77
5.4.1 Measures 79

5.4.2 Sample and Data Collection 88
5.4.3 Data Analysis 91
5.5 Discussion 97
6 Conclusion 103
6.1 Summary 103
6.2 Contribution & Implications 108
6.3 Concluding Remarks 109
Literature 111
Annex 147
I. Interview Guidelines 147
II. Declaration of Anonymization 152
III. Factors used in the Structure Equation Model 153
IV. Preliminary Results Report 155

LIST OF FIGURES

Figure 1: RI Future Research Avenue - based on Berhout et al. 2010 3

Figure 2: Structure of the Dissertation 7

Figure 3: The RI Scheme 13

Figure 4: The RI – Entrepreneurship Framework 25

Figure 5: Exemplary Range of Stakeholders (based on Hall and Martin 2005) 48

Figure 6: H1 Model 78

Figure 7: H2-H7 Model 79

Figure 8: Participants by Region 90

Figure 9: Participants by Position 90

Figure 10: Participants by Field 91

Figure 11: Results H1 Model 94

Figure 12: Results H2-H7 Model 96

LIST OF TABLES

Table 1: Potential Research Questions for Future Research 33

Table 2: Statements related to the Concept of RI 40

Table 3: Overview of Interviewee Details 55

Table 4: Significant Quotations regarding Benefits of and Motivations for Stakeholder Engagement 65

Table 5: Significant Quotations regarding Areas of Uncertainty 67

Table 6: Reflective Factor Loadings H1 Model 93

Table 7: Reflective Factor Loadings H2-H7 Model 95

Table 8: Indirect Effects H2-H7 Model 97

Table 9: Results of Hypotheses Tests 100

LIST OF ABBREVIATIONS

AC	Absorptive Capacity
cU	commercial Uncertainty
dSE	Engagement of direct Stakeholders
DTD	Disruptive Technology Development
iSE	Engagement of indirect Stakeholders
n.s.	not significant
oU	organizational Uncertainty
PLS	Partial Least Squares
RI	Responsible Innovation
RRI	Responsible Research and Innovation
SE	Stakeholder Engagement
SEM	Structure Equation Model
sU	social Uncertainty
tU	technological Uncertainty
U	Uncertainty
VIF	Variance Inflation Factor

1 INTRODUCTION

1.1 Background, Relevance and Research Gap

Innovation is key to long-term economic growth. It also influences peoples' everyday lives. At the organizational level, unique, difficult-to-imitate organizational capabilities have the potential to secure competitive advantage (Eisenhardt and Martin 2000; Ireland and Webb 2007; Teece et al. 1997; Zollo and Winter 2002; Tornikoski et al. 2017). In particular, so-called disruptive technologies, such as advanced biotechnology, nanotechnology and autonomous cars, have the potential to give entrepreneurial organizations an immense competitive advantage. However, such innovation is not automatically societally-desirable and has potentially controversial implications for society and the environment. Nelson and Winter (1982) argue that technological change leads to human progress and generates new externalities that must be dealt with in some way or another. Hence, the question arises of how to responsibly stimulate such technological development.

The discourse on responsible innovation (RI) evolved along with the development of disruptive technologies. In the past, technological progress was seen primarily as a prosperity-bringing process, but this perception has changed in recent years. Nowadays, technological developments, or, more precisely, innovations that arise from such developments, often raise questions regarding their impacts on society and the environment, or their contribution to sustainable development (e.g., the introduction and release of genetically-modified crops in Europe). Because modern society faces various societal and environmental challenges (e.g., The Grand Challenges

defined by the European Commission[1]), one main question for politicians and scientists is how to govern such technological development responsibly. The purpose of theorizing about RI is to contribute to this issue by questioning the current understanding of innovation processes and aligning them with societal expectations, needs and concerns.

Against this background, RI has gained the interest of scholars, practitioners, and policymakers in the past two decades (Grunwald 2011; Schomberg 2013; Stilgoe et al. 2013; Guston 2004; Hellström 2003; Owen et al. 2012), especially during the debate on the development and use of nanotechnology (Morris et al. 2011). This led to the formulation of the term "Responsible Research and Innovation,"[2] which became a significant theme of the EU Horizon 2020 research and innovation program. This led to numerous studies being conducted regarding possible interpretations of the concept and their implementation (e.g., Res-AGorA, SYNENERGENE, PRISMA, Responsible Industry). This development also led to numerous activities to foster research in the field and to support the formation of a community of scholars and practitioners, such as the foundation of the Virtual Institute for Responsible Innovation in 2013 (VIRI Network 2017) and the launching of the *Journal of Responsible Innovation* in 2014 (Guston et al. 2014).

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[1] Challenges defined by the European Commission: Health, demographic change and wellbeing; Food security, sustainable agriculture, marine and maritime research, and the bioeconomy; Secure, clean and efficient energy; Smart, green and integrated transport; Climate action, resource efficiency and raw materials; Inclusive, innovative and secure societies.

[2] In literature, responsible innovation (RI) and responsible research and innovation (RRI) are used as synonyms.

Despite this flurry of activity, the field is still characterized by an absence of consensus regarding the definition of RI. The latter can thus be seen as a contested concept (Blok and Lemmens 2015; Schomberg 2013; Stilgoe et al. 2013). Nevertheless, it can be argued that this contestation constitutes a significant opportunity—especially regarding the aim of this dissertation—because it allows for the exploration of novel research avenues. Taking into account that the focus of activities in the field is on the political and socio-ethical dimension of academic research and development processes (Blok and Lemmens 2015; Lettice et al. 2013), and that the role of entrepreneurial organizations as agents for innovation has been widely neglected, the contestation provides the required openness to connect RI with entrepreneurship research.

Few studies have been conducted on the operationalization of RI in a business context (see e.g., Bolz and König 2018; Blok et al. 2015; Asante et al. 2014; Martinuzzi et al. 2018; Van de Poel et al. 2017), which can be defined as a new, emerging field of research. Berkhout et al.'s (2010) conceptual chain of knowledge flows, depicted in Figure 1 (adapted from Bolz and König 2018), illustrates this focus. The focus of RI research activities has so far been on the "science base" to "technology platforms" stages. The subsequent stages ("technology platforms" to "market needs") have not been examined in detail.

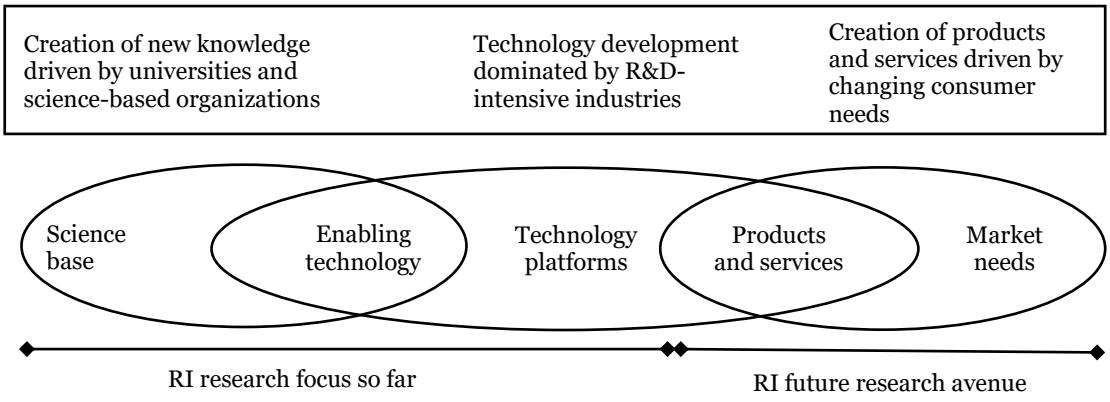


Figure 1: RI Future Research Avenue - based on Berhout et al. 2010

However, these stages in particular should be of high relevance to RI research, because it is in these stages that technologies come into being as products or services. Only the market introduction and diffusion of products and services by entrepreneurial organizations make them available for society on a broad scale; it is at this stage that their full impacts on society and the environment become evident. Basic research would ideally serve as a diverse source for new technologies that could then be further developed into new products and services according to the principles of RI (Bolz and König 2018). It is often during the commercialization stage that concerns about the risks and benefits of innovations arise (Sutcliffe 2011). Hence, it is extremely important to connect RI and entrepreneurship research (see e.g., Bolz 2017). As Schumpeter (1934) and Drucker (1985) argue, it is entrepreneurs who introduce products and services into the markets, making them available to society and thus triggering their impacts on society and the environment. In addition, through innovation and the creation of wealth, entrepreneurs or entrepreneurial organizations take on social responsibility in a wider sense (Volkmann et al. 2010; Baumol 2016; Peterson and Jun 2009). The Schumpeterian concept of "creative destruction" supports this argument, because they destruct existing societal structures, but at the same time create new ones. This indicates that entrepreneurship plays a crucial role in RI. However, RI is widely neglected in the entrepreneurship literature. Besides the necessity for the operationalization of RI to be connected to the field of entrepreneurship research, there is also a need for entrepreneurial organizations to bring their activities into line with societal expectations, needs and concerns. Societal and environmental issues are an increasing focus in business and economics research (Mackey and Sisodia 2014; Norman 2008; Porter and Kramer 2011) and entrepreneurial organizations are increasingly the subjects of public debates concerning societal and environmental problems. Porter and Kramer describe this development as follows: "In recent years, business has

been increasingly viewed as a major cause of social, environmental and economic problems. Companies are widely perceived to be prospering at the expense of the broader community [...]. Companies must take the lead in bringing business and society back together" (Porter and Kramer 2011). Against this backdrop, Corsten and Roth (2012) argue that entrepreneurial organizations need to respond to stakeholders' expectations in their decision making in order to be successful in the long run and to avoid losing social legitimization due to their actions.

RI emphasizes such collaboration as a core component (Bolz and König 2018; European Commission 2014; Schomberg 2013; Blok et al. 2015; Stilgoe et al. 2013), meaning that entrepreneurs and entrepreneurial organizations - who put innovation into practice and hence act as agents of innovation (Drucker 1985; Schumpeter 1934, 1983) - work together with a wide variety of stakeholders throughout the process of discovering, evaluating and exploiting opportunities. Dew and Sarasvathy (2007, p. 267) identified this intersection of stakeholder theory and entrepreneurial innovation as a "potentially rich arena for research."

1.2 Research Aim and Questions

With its premise of early stakeholder engagement in the innovation process, RI could be of immense relevance to entrepreneurial organizations with regard to their success and failure. However, the question of how to operationalize RI within entrepreneurial organizations remains unanswered. Against this backdrop, this dissertation adopted an exploratory approach and started with the following general research question:

> Q1: How is RI related to the field of entrepreneurship and how can it be operationalized in this context?

Thus, the initial effort was to connect RI and entrepreneurship research on a conceptual level to shed light on the operationalization of RI, which was then set in the context of potential RI operationalization strategies in the advanced biotechnology sector, which is a field of disruptive technology development. Building on the focus of stakeholder engagement in RI and a special interest in the field of advanced biotechnology, the following question was posed:

> Q2: What role do stakeholders play in entrepreneurial organizations during the disruptive technology development process?

On the basis of the insights gained from answering this research question, which was done by means of a qualitative, interview-based research approach, the focus of research was further narrowed down by asking:

> Q3: How does stakeholder engagement influence the uncertainty of disruptive technology development processes at entrepreneurial organizations?

1.3 Structure of the Dissertation

This dissertation is divided into two parts. It starts with explorative theoretical and empirical research, and ends with in-depth empirical research. In Part 1 the connection between RI and entrepreneurship research is pioneered, with a stress on the need to integrate entrepreneurship research into RI. To strengthen the theoretical approach and to connect RI and entrepreneurship, empirical data from a content analysis of a workshop report was used to gain initial insights into potential operationalization strategies of RI in an entrepreneurial context. This approach was intended to facilitate understanding of the potential role of RI in business and economics research. Based on the insights presented in part 1 and a focus on the role of stakeholders during the entrepreneurial process,

in part 2 the relevance of RI in practice is examined. This was achieved by first applying a qualitative empirical research approach, in which in-depth interviews result in hypotheses that were then tested using a structural equation model approach. This mixed-methods approach falls under the "confirm and discover" category (Bryman 2016) for combining qualitative and quantitative research, which entails using qualitative data to generate hypotheses and using quantitative research to test them within a single project. The overall structure of the dissertation is illustrated in the following figure.

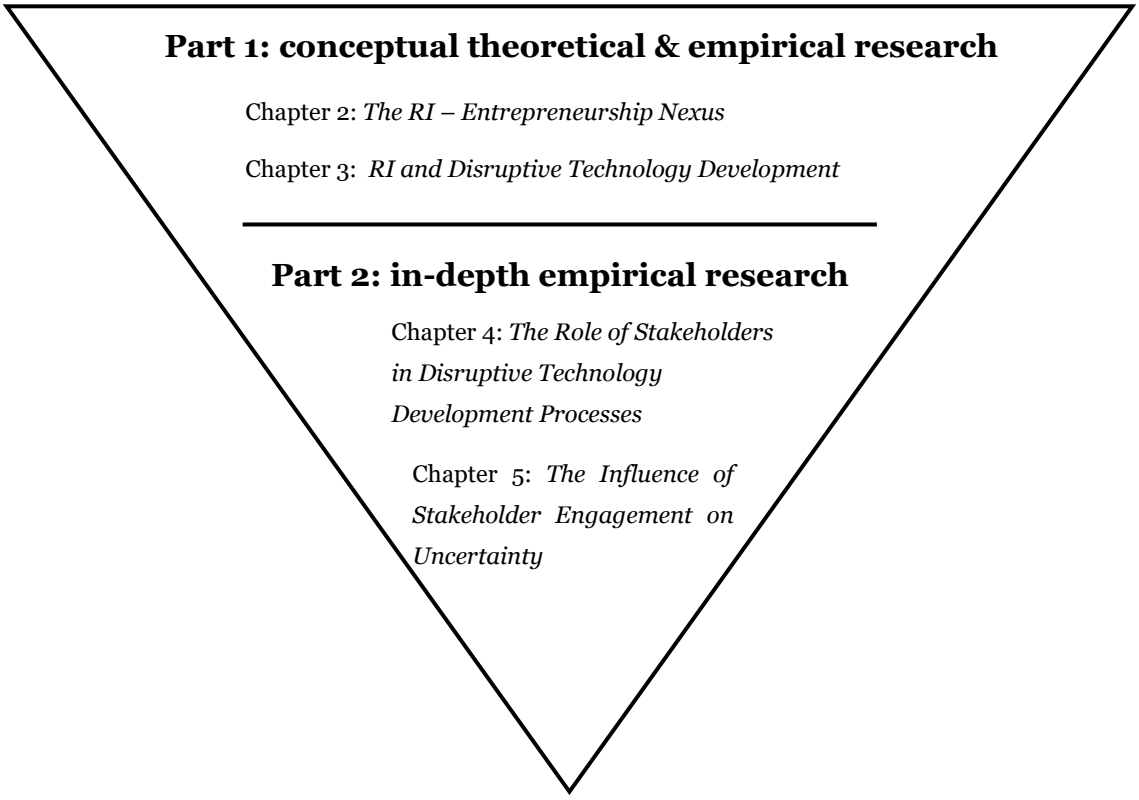


Figure 2: Structure of the Dissertation

Having provided a short overview of the organization of the dissertation, the following is a more detailed description of the structure.

To connect the concept of RI with business and economics research, two distinct approaches were adopted for the research described in part 1 of this

dissertation. First, in chapter 1, RI and entrepreneurship research are connected on a conceptual level. In chapter 2 the argument concerning the lack of research on RI in the later stages of innovation chains is developed and entrepreneurship is identified as an agent for innovation. Starting from a definitional point of view, three aspects—design innovation, normative ends and collaborative reflection—of RI are identified to pioneer the connection of RI with entrepreneurship research. This identification informs a framework that connects both fields. Subsequently, in chapter 3, a content analysis of a workshop report is used to determine practical operationalization strategies of RI in an entrepreneurial context, with a strong focus on collaboration as a key approach to RI.

To further examine this key aspect of RI, in part 2 the focus is on the role of stakeholders in entrepreneurial organizations and springboards from the framework developed in part 1. Seeing the exchange of information that can be triggered through stakeholder engagement as a pathway to reducing uncertainty, part 2 comprises an explicit examination of the influence of stakeholders on the uncertainties of the disruptive technology development processes of entrepreneurial organizations. Such uncertainties lie at the heart of RI, especially when related to social uncertainty - meaning the impacts of such technology on society. Hence, a key argument for including the concept of RI in entrepreneurial organizations is the reduction of uncertainty through collaborative reflection and information exchange. To further examine this argument, an empirical research approach was utilized. This is described in chapter 4. Conducting nine in-depth interviews with high level business representatives made it possible to examine the role of various stakeholder categories on uncertainties in entrepreneurial organizations that are involved in disruptive technology development (DTD), namely advanced biotechnology/synthetic biology. Uncertainties in fields that are engaged in disruptive technology development are high by nature. They were thus ideal research arenas for this research.

In chapter 5, the hypotheses that were developed based on the insights generated by the qualitative study are presented, along with the details of their development and testing by means of an explorative structural equation model approach, capitalizing on primary data gathered through questionnaires. Finally, chapter 6 sums up the considerations contained in the preceding chapters and constitutes conclusive interpretation of the results.

PART 1

2 THE RI - ENTREPRENEURSHIP NEXUS

In this chapter the concept of RI is connected to entrepreneurship research and the operationalization of RI is explored. In order to unite the two domains, various interpretations of RI are scrutinized. The concept is shown to be composed of three aspects: design innovation, normative ends and collaborative reflection. After providing an overview of the RI literature, the notion of entrepreneurship is examined in light of this RI scheme. Furthermore, a theoretical framework of how to integrate normative ends and collaborative reflection into the entrepreneurial process is outlined. The latter is understood as the design process in which opportunity is transformed into innovation. The emphasis is on the potential of collaboration to enable entrepreneurial organizations to take normative aspects into account, making the entrepreneurial process more inclusive, and its outcomes more sustainable and societally-desirable by moderating the process.

2.1 The RI Concept

The contestable nature of RI is represented by its different interpretations in the literature. One of the most influential interpretations is provided by Schomberg (2013). His concept of RI is anchored in European policy processes and, in particular, in the Treaty on European Union. He defines RI 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 (in order to allow a proper embedding of scientific and technological advances in our society)"

(Schomberg 2013, p. 63). With regard to the implementation of his RI framework, he refers to key fields that need to be addressed: (1) technology assessment and foresight; (2) application of the precautionary principle; (3) normative/ethical principles related to design technology; (4) innovation governance and stakeholder involvement; and (5) public engagement. Another seminal work on RI is an article by Stilgoe et al. (2013), in which the authors take a broader approach to RI, using Schomberg's definition as a basis. They argue that RI "means taking care of the future through collective stewardship of science and innovation in the present" (Stilgoe et al. 2013, p. 1570) and develop an RI framework by defining four dimensions of RI: (1) anticipation (identification of potential intended or unintended impacts of innovations); (2) reflexivity (understanding the role of innovators in society and a reflection on their activities); (3) inclusion (including a wide variety of stakeholders in the innovation process); and (4) responsiveness (the ability of an innovator to adapt or change in response to stakeholders and public values, and changing circumstances).

A third important interpretation of RI is provided by the European Commission, which included it in the Horizon 2020 program. In its framework on RI, it is stated that RI "means that societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of European society" (European Commission 2014, p. 1). In addition to this definition, the European Commission outlines six dimensions of RI: (1) engagement; (2) gender equality; (3) science education; (4) ethics; (5) open science; and (6) governance.

This overview of the most important interpretations of RI illustrates its contestable character. Nevertheless, one can identify common aspects throughout these three interpretations of RI. One of these is that they all refer to RI as an intrinsic part of the design process of innovation and not as

an external regulatory instrument. Schomberg puts it well when he concludes that "[i]nstead of a 'hurdle', RI should become a research and innovation 'design' strategy which drives innovation and gives some 'steer' towards achieving societally-desirable goals" (Schomberg 2013, p. 72). For broader overviews of the RI literature, see Ribeiro et al. (2017) and Pellé (2016).

From a dimensional point of view, one can identify three common dimensions of RI—process, normativity and collaboration (Bolz and König 2018)—that are represented in the most important definitions of RI given above, and which can also be found in the RI scheme outlined in this work. Nevertheless, this author wants to move away from the definitional debate by taking the broader debate on RI, as well as various dimensions and affected fields, into account. Because the aim is to formulate a universal conceptualization of the connection of RI and entrepreneurship, it must emerge from a broad interpretation of RI, in which it is understood as a field in which a variety of actors engage in a collaborative process to reflect on normative ends to inform the design of innovations.

2.2 Relations between RI and Entrepreneurship

To unite RI and entrepreneurship, it is necessary to build on the idea that entrepreneurship is an agent of innovation. Although the pioneers of economic theory recognized the relevance of and the nexus between technological progress and economic growth, a more intensive examination of the topic of innovation did not take place until Schumpeter (1934) tackled the subject. He identified innovation as the strategic stimulus for economic development, which was put into practice by entrepreneurs realizing new factor combinations - new products, new processes, new production methods, new markets, new sources of supply, or new forms of organization (Schumpeter 1934, 1983). This close connection between entrepreneurship

and innovation is also emphasized by Drucker, who describes innovation as "the specific instrument of entrepreneurship [...] that endows resources with a new capacity to create wealth" (Drucker 1985, p. 27). Hence, entrepreneurship can be understood as an agent of innovation, which generates wealth and influences peoples' everyday lives.

As noted above, this dissertation is premised on a broad interpretation of RI to connect the concept with entrepreneurship research. Based on this understanding of RI, the concept is divided into three main aspects - design innovation, collaborative reflection, and normative ends (see Figure 3 - also compare with Bolz and Bruin 2019), which will be discussed separately in relation to entrepreneurship. Although all three aspects are strongly connected, this approach is used for clarity purposes. Later, while developing the framework, the aspects will be illustratively reconnected to draw the "big picture."

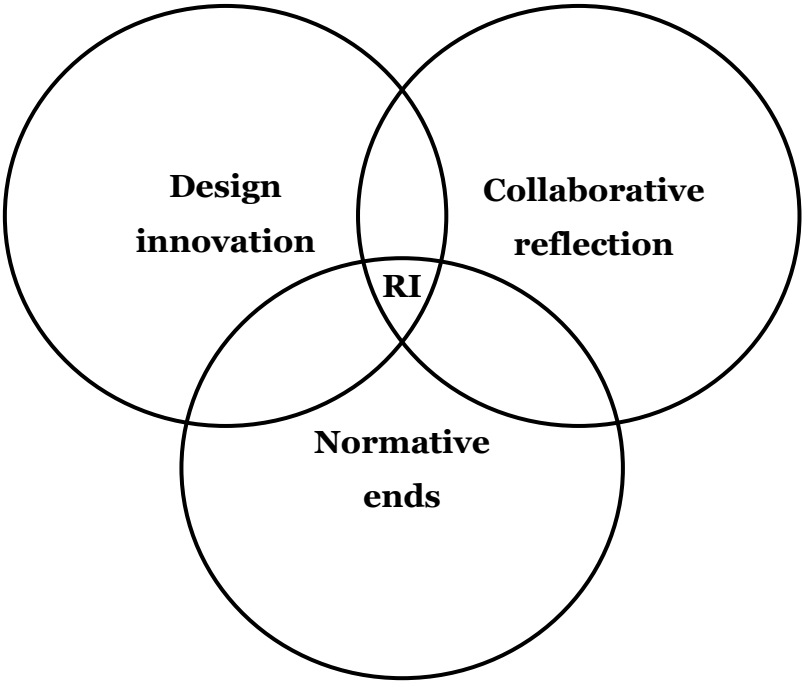


Figure 3: The RI Scheme

2.2.1 Design Innovation

Because entrepreneurship is understood as the agent of innovation - whether it takes place when starting a new organization or within an existing organization (Knight 1987; Rule and Irwin 1988) - it is the entrepreneurial process that determines the design innovation.

There are a variety of approaches to portraying the entrepreneurial process. Sometimes it is described, in a conservative way, as the creation of a new organization with a focus on activities such as acquiring capital and establishing the organizational structure (e.g., Freear and Wetzel 1990; Hellmann and Puri 2002). However, it can also be understood in a broader sense. Based on the premise that entrepreneurship is not primarily about setting up new enterprises or organizations, but is rather ultimately about the exploitation of opportunities to create goods and services, Shane and Venkataraman (2000) state that "the field involves the study of sources of opportunities; the processes of discovery, evaluation, and exploitation of opportunities; and the set of individuals who discover, evaluate and exploit them" (Shane and Venkataraman 2000, p. 218). In a similar but more practically-oriented way, Johnson (2001) states that "entrepreneurship, in its narrowest sense, involves capturing ideas, converting them into products and/or services, and then building a venture to take the product to market" (Johnson 2001, p. 138). Both perspectives can be linked back to the ideas of Herbert Simon (1996, 1993, 1959), a Nobel Prize winner in economics. He describes design as the exploration of new alternatives that involves "a problem-solving process that seeks to discover, invent, design or assemble new products or courses of action" (Simon 1993, p. 137). Furthermore he asserts that such exploration encompasses "the entire decision-making process, starting with the identification of problems, continuing with the design of alternative courses of action, and leading ultimately to effective implementation" (Simon 1993, p. 141). A concept that illustrates Simon's

consideration is design thinking, which is structured into three phases, or so called "spaces," which are labeled as "[1] 'inspiration,' for the circumstances (be they a problem, an opportunity, or both) that motivate the search for solutions; [2] 'ideation,' for the process of generating, developing, and testing ideas that may lead to solutions; and [3] 'implementation,' for the charting of a path to market" (Brown 2008, p. 4). Hence the concept reflects the considerations of Shane and Venkataraman and Johnson on entrepreneurship, as well as Simon's ideas on design as a process. However, it not only represents the entrepreneurial process, but also ideas regarding RI. With its human-centered approach, design thinking takes human behavior, needs and preferences into account, which can lead to societally-desirable solutions (Brown and Wyatt 2010). Hence, design thinking is a useful springboard for a framework to unite RI and entrepreneurship.

Shane and Venkataraman also include the set of individuals who discover, evaluate and exploit opportunities. Apart from this opportunity-seeking approach to entrepreneurship, there is another literature stream. Effectuation attracts growing interest in entrepreneurship research (e.g., Brettel et al. 2012; Chandler et al. 2011; Chiles et al. 2008; Read et al. 2009; Sarasvathy 2001; Sarasvathy et al. 2014). In her article, which can be seen as the foundational article on effectuation in entrepreneurship research, Sarasvathy (2001) focuses on the individual in her attempt to understand the logic behind entrepreneurial decision-making.

While in the past most researchers focused on the set of individuals (Venkataraman 1997), this dissertation is primarily concerned with the conceptual and procedural level of entrepreneurship and, therefore, the set of individuals is not part of the examination. This shift in focus is in line with a trend in entrepreneurship research to examine entrepreneurship as a concept rather than focusing on the individual level, as stated by Brem

(2011). This is not to say that the individual level and the effectuation approach to entrepreneurship are not relevant to research on the nexus of RI and entrepreneurship. Quite the contrary, in the discussion section of this chapter the potential for future research in this area is noted.

In the context of entrepreneurship, the design innovation aspect of RI is understood as the transformation of opportunity into innovation through entrepreneurial activities, whether this takes place when starting a new organization or within an existing organization. This involves the search for ideas and the discovery of opportunities, the exploration of new alternatives and the implementation and market introduction of products and services.

2.2.2 Normative Ends

Talking about normative ends in a business context inevitably leads to the discussion on sustainability in relation to organizational activities (Wikström 2010), especially on corporate social responsibility (CSR) (for an overview, see Lindgreen and Swaen 2010; Crane et al. 2017; Luke 2013; Welford 2005). However, CSR is often implemented with adherent means that supplement core business activities, without reflection on the core activities, in contrast to RI. Therefore, a more general normative approach was chosen to explore the "normative ends" dimensions in this dissertation. More precisely, the ethics of responsibility by Max Weber (Weber 1919; Weber and Runciman 1995) are taken into consideration. In his ethics of responsibility, Weber emphasizes the importance of responsibility for the consequences of one's actions. This focus on the consequences of actions plays an important role in the context of RI and entrepreneurship, because the impacts of innovations on society and the environment are, *inter alia*, the consequences of entrepreneurial actions that influence the transformation of opportunities into innovations. This ethical imperative of RI is captured by Pandza and Ellwood (2013), who state that "the human

capacity to innovate largely surpasses the capability for innovation that has sustainable outcomes for society. Concerns about intended and unintended impacts of new technologies explain growing calls for responsible innovation" (Pandza and Ellwood 2013, p. 1112). Schomberg also pays much attention to the consequences and impacts of activities that lead to innovation, and especially the impacts of innovation itself, which can be seen as a universal feature of RI. He highlights "the right impacts and outcomes" (Schomberg 2013, p. 56) of the innovation process. This shows the importance of the anticipation of consequences, which is essential already in the early phases of the process. With regard to the normative ends of entrepreneurship, this means that attention should be paid to not only the commercial sustainability, but especially to the societal impacts and the desirability of innovations.

As normative ends can vary from context to context and culture to culture, it is difficult to make universal assertions about them. This is also reflected in the RI literature. For example, Stilgoe et al. (2013) argue that "in different areas of innovation, and in different cultural contexts, different values will be more or less pertinent, and they may be conflicted" (Stilgoe et al. 2013, p. 1577). In a similar vein, Grunwald (2011) states that "what 'responsible' means in a specific context and what distinguishes 'responsible' from 'irresponsible' or less RI is difficult to identify. The distinction will strongly depend on values, rules and customs, but also on the knowledge available and its validity, and will vary according to different contextual and actor conditions" (Grunwald 2011, p. 17). Thus, in both articles, the authors are reticent to explicitly define the normative end of RI. In contrast, Schomberg posits a general set of moral principles to guide innovation processes that are based on the acceptability, desirability and sustainability of innovation processes and their outcomes. For him such "right impacts" are found in the normative targets stated in the Treaty on the European Union, which have been democratically agreed on. Nevertheless, using the definition of

opportunity, namely "future situation which is deemed desirable and feasible" (Stevenson and Jarillo 1990, p. 23) and Simon's understanding of design, namely that "everyone designs who devises courses of actions aimed at changing existing situations into preferred ones" (Simon 1996, p. 55), one might argue that, from a Weberian point of view, this could mean that the consequences of entrepreneurial action should lead to a future situation that is desirable for society, implying that the desirability is subject to societal negotiations. Therefore, collaborative reflection might not solely help to find alternative paths towards innovation, but also to negotiate their normative ends. One value set that reflects such normative ends that has been democratically agreed on has attracted much attention by researchers, practitioners and policymakers since its enactment in 2015. The UN Sustainable Development Goals (SDGs) are a set of 17 linked reference goals for the 2015–2030 period (Le Blanc 2015) with the aim of ending poverty, protecting the planet and ensuring prosperity for all. Hence, one might break down the normative ends addressed in RI to the SDGs and the principles of sustainable development, as defined by Brundtland (1987) (Bolz and König 2018).

In entrepreneurship research, two emerging concepts can be identified that strongly deal with such normative ends: social entrepreneurship (Brinkerhoff 2000; Mair and Martí 2006; Ney et al. 2014; Peredo and McLean 2006; Volkmann et al. 2012) and sustainable entrepreneurship (Dean and McMullen 2007; Hall et al. 2010; Schaltegger and Wagner 2011; Poldner et al. 2016). The boundary between the two concepts is blurred. Schaltegger and Wagner (2011) placed a high priority on environmental and social benefits as business goals for both concepts. From the dimensional perspective of the "triple bottom line" (Elkington 1997), social entrepreneurship focuses primarily on the social dimension, whereas sustainable entrepreneurship can be seen as a concept that takes all three dimensions into account. Social entrepreneurship could thus be seen as a

subcategory of sustainable entrepreneurship. In general, there is a dearth literature dealing with the contribution of entrepreneurship to a more sustainable society through innovation (e.g., Larson 2000; Cohen 2006; Cohen and Winn 2007; Schaltegger et al. 2016; Schaltegger and Wagner 2011; Schaltegger et al. 2016). Nevertheless, such approaches become increasingly important at a time when the concept of sustainable development and the SDGs are omnipresent.

Although concepts with a strong normative perspective already exist in entrepreneurship research, it is argued that the connection of RI and entrepreneurship is important, because RI has an additional strong focus on collaborative reflection on the normative ends of the activities and outcomes of processes related to design innovation that, from a RI perspective, need to be agreed on (e.g. through collaborative reflection). Furthermore, it can be argued that both domains - entrepreneurship and RI - can mutually learn from each other. Entrepreneurship literature can impart how to exploit opportunities, in the case of sustainable entrepreneurship in a manner that follows the principles of sustainable development. RI introduces collaborative reflection as an additional core aspect to govern this process by involving various actors.

2.2.3 Collaborative Reflection

Starting from a general perspective, collaboration can be seen as essential to meeting sustainability goals and fostering systemic change (Senge et al. 2007). Furthermore, collaboration can be viewed as a new kind of coordination governing the entrepreneurial mode of exploitation. This is particularly important in times of globalization, when governments are

often not able to effectively deal with sustainability issues due to the geographical range and the timeframe of such issues (Senge et al. 2007).[3]

Collaboration in the context of entrepreneurship means to collaborate with other actors within the entrepreneurial ecosystem[4]. Isenberg (2011) defines six domains of the entrepreneurship ecosystem: policy, finance, culture, supports, human capital and markets. Every single domain is represented by actors who operate within this domain. These actors can be referred to as stakeholders, which can be defined as "any group or individual that can affect or is affected by the achievement of the organization's objectives" (Freeman 1984, p. 46). This definition emphasizes the multidirectional interdependencies between the entrepreneurial organization and its ecosystem. Thus, collaboration during the entrepreneurial process means to integrate stakeholders and to open up the process. Possible stakeholders who could participate in the collaboration are, for example, customers, business partners, financial institutions, incubators and accelerators, higher educational institutions, governmental organizations, non-governmental organizations, and local communities (e.g., Neck et al. 2004; Cohen 2006; Isenberg 2011; den Hond et al. 2012). Stakeholder engagement can be defined as "practices the organization undertakes to involve stakeholders in a positive manner in organizational activities" (Greenwood 2007, p. 315). When starting a new venture, regardless of whether one is building a start-up or within an existing organization, collaboration with stakeholders can be seen as crucial to the success of the venture because, for instance, there is a need to have access to financial or human capital (Kim

[3] Senge et al. (2007) furthermore name the fragmentation of democratic societies as a reason for the ineffectiveness of governments regarding sustainability issues.

[4] The term ecosystem was introduced into the business context by James Moore 1993 as an analogy to the biological ecosystem, setting organizations into a wider context – the business ecosystem.

et al. 2006; Cooper et al. 1994). Some of these relationships are more obvious than others; for example, the relationship with investors (Arthurs and Busenitz 2003; Shane and Cable 2002) is more tangible than the one with society (Steurer 2006; Steurer et al. 2005).

However, collaborative reflection is not exclusive to RI. The importance of networks for entrepreneurial organizations striving for sustainable development has been examined, for example, by Cohen (2006). Regarding their importance or, more precisely, the actors within these networks, who can be referred to as stakeholders, Schaltegger and Wagner (2011, p. 225) state that "[s]takeholder demands go beyond narrow economic interests of shareholders and are the ultimate sources of entrepreneurial opportunities for sustainability innovation [...], discovery and exploitation of which is at the core of sustainable entrepreneurship [...]." They identify the integration of stakeholders as a crucial capability for sustainable entrepreneurship. However, from an RI perspective, the integration of various stakeholders, the reflection on alternative paths to innovation and their impacts are fundamental to enabling entrepreneurial activities that lead to desirable and sustainable innovations. Collaborative reflection is not just one crucial capability, but the core capability. With regard to shaping technology and innovation towards desirable futures, Grunwald (2014, 2011) advocates for such reflection as the signature feature of RI. Stilgoe et al. (2013) also see such a reflexivity perspective as an essential part of RI and integrate it into their RI framework. They state that reflexivity "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).

Such reflexivity is an essential part of the definition of collaboration given by Gray (1989), who defines it as "a process through which parties who see different aspects of a problem can constructively explore their differences

and search for solutions that go beyond their own limited vision of what is possible" (Gray 1989, p. 5). Thus collaboration is about addressing shared problems and achieving shared goals at an interorganizational level (Selsky 1991), but also about mutual learning within the network of actors (Beeby and Booth 2000; Bergh 2008; Gulati 1999; Powell et al. 1996).

In the context of this dissertation, collaborative reflection is understood as the effort of a variety of actors to jointly explore alternative paths towards innovation, and their consequences and impacts for society and the environment, as well as the reflection on the normative ends that moderate the design process of innovation and its outcomes. Such activities call for coordination. From an entrepreneurial perspective, this means that the entrepreneurial organization has to manage such collaborative reflection constructively. Thus, entrepreneurial organizations are not merely agents of innovation, but also hold coordinating agency.

To illustrate how the RI scheme - consisting of design innovation, normative ends and collaborative reflection - might help to identify opportunities or problems, alternative paths towards innovation and their consequences and impacts on society and the environment, a framework is outlined in the following section that unites the fields of RI and entrepreneurship.

2.3 An RI-Entrepreneurship Framework

In order to unite the domains of RI and entrepreneurship, an RI–entrepreneurship framework is developed in this section. It illustrates how the entrepreneurial process can be moderated through collaborative reflection to attain the normative ends of RI. With this objective, the framework exemplifies how to bring a wide variety of stakeholders together to jointly reflect on alternative options and ways to achieve a desirable future state. For the entrepreneurial organization, this involves

collaboration with a set of stakeholders during the entrepreneurial process to stimulate a transformative development, with a "win-together approach" (van Marrewijk and Werre 2003, p. 112) to orchestrating the various interests and expectations of stakeholders.

2.3.1 The Role of Stakeholders within the Framework

As noted above, a wide variety of stakeholders are active in the various domains of the entrepreneurial ecosystem, who, in terms of RI, should be involved in the design of innovation to make it societally robust. Such stakeholders might have different or common interests that need to be aligned during the entrepreneurial process to attain RI goals. Therefore, entrepreneurial organizations need to consider the social identities of stakeholders and the differing expectations, needs and interests connected with these identities, as well as their relation to the firm (Crane and Ruebottom 2011; den Hond and Bakker 2007). However, stakeholders might change during the process. Their expectations, needs or interests might also change or be redefined during the process of collaboration (Wood and Gray 1991). The main challenges regarding the need to take a wide variety of stakeholders into account are, on the one hand, to allow a broad reflection on alternative paths and impacts in order to align products and services with societal goals, and, on the other hand, to facilitate a successful entrepreneurial organization at the same time. The vital prerequisite for this process is a willingness on the part of each stakeholder to build a network to promote RI goals; namely one that contributes to reflection on normative ends to inform the design innovation. Senge et al. (2007) outline three interconnected types of work that are necessary for successful collaboration: conceptual, relational and action-driven. The conceptual work comprises a systemic perspective. The actors need to commit to a shared vision, within which they pursue their individual goals, but also consider the larger perspective and the goals of the other actors. In

addition, “the network must be able to build a conceptual infrastructure that supports the systemic perspective” (Manring 2007, p. 330). For this relational work, it is important to support the promotion of “trust, mutuality and joint learning” (Senge et al. 2007, p. 47), for instance by creating spaces for mutual exchange and learning. According to Senge et al., this exchange enables the actors to explore differences, to agree on the rules of collaboration and to handle conflicts. This conceptual and relational work provides for collaborative, action-driven work that enables consensus-based decision-making.

In the context of the framework, this means that the design of collaborative reflection activities is key to promoting sustainable and societally-desirable innovation. In the following, the manner in which such collaboration can be operationalized, such that alternative paths towards innovation and its normative ends are taken into account, is elucidated.

2.3.2 The Process Dimension of the Framework

The trinomial design thinking process, consisting of the inspiration, ideation and implementation phases, is the core of the framework (see Figure 4). Because it is hard to make a clear distinction between the different phases—where one ends and the other begins—they are illustrated as overlapping entities. In general, the entrepreneurial process is understood as the design process in which opportunity is transformed into innovation. Against this background, in this section the manner in which the entrepreneurial process can be triggered towards innovation that is societally-desirable is described.

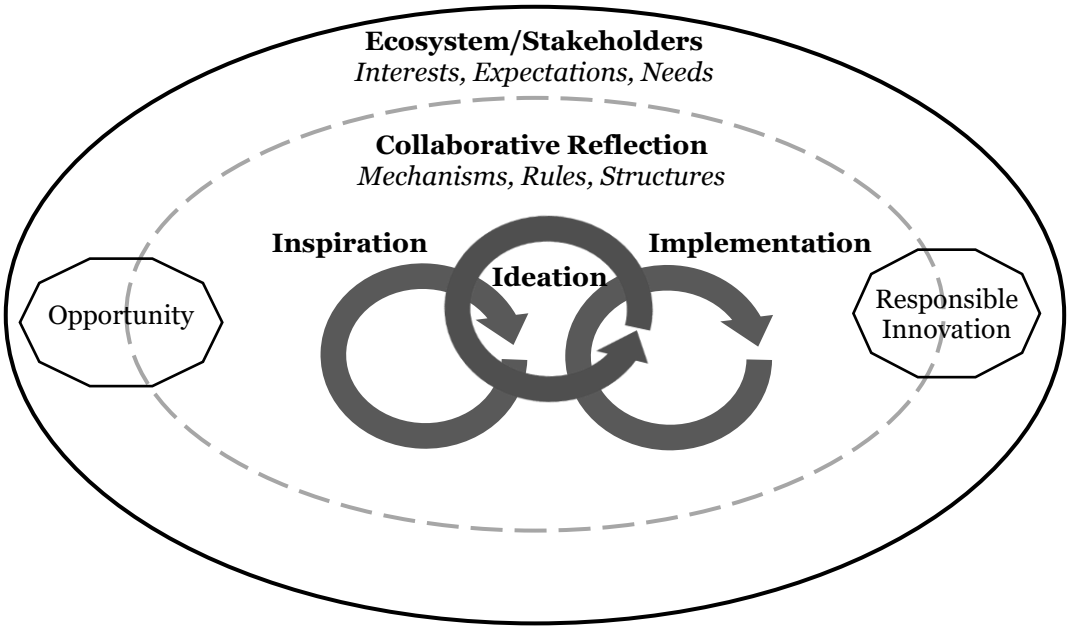


Figure 4: The RI – Entrepreneurship Framework

The inspiration phase is described as the "circumstances […] that motivate the search for solutions" (Brown 2008, p. 4). From the perspective of RI, this might mean that the inspiration phase is influenced mainly by the search for solutions for societal and/or environmental issues. The European Commission narrowed down the field of search to the "Grand Challenges" it defined. Nevertheless, in the context of RI, the purpose of new products and services is at the heart of the search for new ideas. Against this background, Owen et al. (2013) illustrate various aspects by formulating questions that should be addressed while thinking about the purpose of innovation in the context of RI: "Why do it? Who might benefit and how? Will such benefits be equitable? Will it confer burdens to some or many? In whose interests is it being undertaken and what are the motivations of those involved? Do we (as a society) want it?" (Owen et al. 2013, p. 34). These questions highlight the society-centered and impact-oriented perspective of RI.

Throughout the entrepreneurial process, the acquisition, provision and use of resources is a key factor for success (Schumpeterian resource-based view

- “new factor combinations”). During the inspiration phase especially, information is the most important resource to be gained and combined in an effective way. It is important to search for ideas on how to exploit opportunities within a society-centered scope. Collaboration can play a crucial role in acquiring such information. Stakeholders can help to widen the scope and to explore entrepreneurial opportunities, for example, by providing information, knowledge or access to infrastructure or societal groups. For instance, methods from the Design Thinking approach (e.g. field research) can support the common exploration of societal needs or problems and the search for society-centered solutions (Brown 2008; Brown and Wyatt 2010). Taking societal and environmental considerations into account, and including a society-centered view while searching for information to identify opportunities, presumably leads to more inclusive, sustainable and responsible solutions. Stakeholders can be seen as a source of new ideas during the inspiration phase by providing information.

Starting from such a society-centered and purpose-driven search for ideas, the ideation phase comprises the search for concepts to realize solutions for identified opportunities. From the design thinking perspective, this phase is defined as “the process of generating, developing and testing ideas that may lead to solutions” (Brown 2008, p. 4). In this phase, responsible entrepreneurial activities include reflecting on possible solutions in relation to their impacts on a societal level. It is not enough to take a human-centered approach, as in the design thinking process. A more holistic society-centered perspective should be targeted to include a wide range of impacts of new services and products.

As soon as the needs or problems are identified, stakeholders can help to find ways to serve or solve them (Chesbrough 2003; Hippel 2005). Collaborative reflection can support a divergent thinking process to generate and evaluate options during the ideation phase regarding their

feasibility and desirability, as well as to identify the impacts of possible solutions. It can also be employed to identify methods for an intelligent design of products or services and their production processes (e.g. industrial ecology, cradle to cradle) that provide not only major environmental but also societal and economic benefits (Graedel and Allenby 1995; McDonough and Braungart 2002; Esty and Porter 1998).

This is also true for the implementation of possible solutions. While "charting of a path to market" (Brown 2008, p. 4), the impacts of innovations need to be taken into account. However, even more importantly, the impacts of the processes that enable new products and services, such as sourcing, production and disposal (Vermeulen and Seuring 2009; Vermeulen and Ras 2006), need to be assessed.

In this manner the concept of RI, with the three aspects outlined above, becomes an intrinsic part of entrepreneurship. During the process of design innovation, the entrepreneurial organization and its stakeholders collaboratively reflect on alternative paths towards innovation, their impacts and the normative ends of the process, and its products and services. This perspective is closely linked to the sustainable development paradigm and the SDGs, and facilitates inter- and intra-generational equity (Baumgartner and Ebner 2010; Wheeler et al. 2017; Pinelli and Maiolini 2017).

This nexus between RI and entrepreneurship is understood as the transformation of opportunities into innovation through entrepreneurial action moderated by collaborative reflection on the normative ends of the process and its outcomes.

2.3.3 Examples of the RI–Entrepreneurship Nexus

To illustrate how the three phases of the framework can be understood, in this section examples are given and linked to the SDGs to emphasize their normative ends.

Finding inspiration for the search for solutions is the first step towards innovation and, with respect to RI, this search is inspired by societal challenges. A project that was clearly inspired by such a societal challenge was the Ocean Cleanup project (The Ocean Cleanup Project 2017). Addressing the problem of plastic pollution of the oceans, the project organizers aim to develop a passive system to clean up the subtropical gyres, also known as the world's "ocean garbage patches." It addresses SDG number 14: Conserve and sustainably use the oceans, seas and marine resources.

The "One Dollar Glasses" project (One Dollar Glasses Project 2017) to provide affordable glasses to the poorest in the world also addresses societal challenges throughout the ideation phase. Instead of producing the glasses centrally and distributing them, the project team developed a concept in which the frames were produced and the glasses were assembled and customized locally. This business model (1) grants poor people access to affordable glasses and (2) generates jobs. Taking societal challenges as a source of inspiration as well as seeing them as part of the ideation phase, enabled the project team to address these challenges from two angles. The project addresses two major SDGs: (1) Goal 3: Ensure healthy lives and promote well-being for all at all ages and (2) Goal 8: Promote inclusive and sustainable economic growth, employment and decent work for all.

An example that can be located at the interphase of ideation and implementation is the case of Fairphone (Fairphone 2017). The Dutch-based start-up developed a sustainable business model by collaborating

with key stakeholders. Fairphone questions the supply chain of modern consumer electronics. As far as possible, the company attempts to source conflict-free minerals and promote workers' rights. Furthermore, their team applies design principles during the entrepreneurial process that positively influence the longevity and reparability of their product - an up-to-date smartphone. The use of global asymmetries, such as in wealth allocation or in labor and environmental regulations, in the production of goods or provision of services, is often premised on unsustainable and irresponsible paths of exploitation, triggering negative impacts on society and the environment. The case shows that for the Fairphone team it was important to avoid such negative effects through close collaboration with stakeholders affected by the implementation of the venture to collaboratively reflect on the normative end during the design of their product. The project has strong connections to the SDGs, to be precise to goal 12: Ensure sustainable consumption and production patterns, and goal 17: Revitalize global partnership for sustainable development.

All three examples showcase how societal aspects can be integrated into the various phases of the entrepreneurial process to attain the SDGs as the normative ends of RI.

2.4 Discussion

An important issue with the governance of technology, whether it is on a macro or a micro level, is often the lack of information and control (Collingridge 1982). Precise predictions on the impacts of technologies cannot be made until they are developed and used; however, as soon as they are, control becomes difficult, for example, due to path dependencies. RI, with its collaborative approach, seeks to open up science and innovation processes and to consider purposes, values and motivations of innovation to overcome such dilemmas. Whereas the focus of RI activities has so far

been mainly on the macro level and the early stages of the chain of knowledge flows within innovation, one can argue that the later stages—and especially the phase in which products or services are created and marketed—should be equally important. This is because it is only when products and services are introduced into the markets by entrepreneurial activities and diffused effectively, thus becoming available for society on a broad scale, that their full impacts on society and the environment become evident. To contribute to the debate on the implementation of RI in these later stages, in this chapter the meaning of RI was examined and connected with entrepreneurship research. Moreover, a framework was developed for its operationalization in entrepreneurial organizations.

It is argued that sustainable development is a core theme in RI. Normative anchor points are also of high relevance to RI. This is also evident in two seminal articles on RI. Both Schomberg (2013) and Stilgoe et al. (2013) refer to sustainable development while outlining their understanding of RI and delineating their definitions. While Stilgoe et al. (2013), rather than explicitly defining the normative ends of RI, base their RI framework on second-order normative commitments to democratization, here it is argued that sustainable development is a good fit for the purpose of this chapter, namely to contribute to the debate on the operationalization of RI in an entrepreneurial context, because it has become a tangible concept in the business environment. In stakeholder workshops, RI is often perceived as a rather vague or abstract concept with which entrepreneurial organizations cannot or do not want to engage. Sustainable development might thus act as a springboard for the operationalization of RI in an entrepreneurial context.

Even though the integration of RI into the entrepreneurial process sounds like a valuable idea, one could ask why organizations should undertake such an effort to follow the responsible entrepreneurship approach. Several

barriers could hinder the application of the suggested framework, or at least parts of it. For example, a lack of resources could inhibit a partial or complete integration, especially for start-ups or early-stage ventures, in which the focus is often on economic survival; or the required openness of the entrepreneurial process to stakeholders that could lead to the depletion of information asymmetries and thus to a loss of competitive advantage (Blok et al. 2015). Nevertheless, there could also be drivers that promote such an endeavor. The past has shown that, in particular, products using emerging technologies with which society is familiar are not accepted and thus do not lead to any returns (e.g., genetically-modified organisms in the food sector (Gaskell 2010).

The integration of a broad variety of stakeholders could lead to a better alignment of products or services with societal goals and expectations, and thus help to avoid such setbacks. However, it is not only organizations that deal with emerging technologies that could benefit from such an approach. Integrating the principles of RI into the entrepreneurial process allows for a better understanding of the needs and concerns of society and also uses it as a source of new ideas. This could reduce the uncertainty connected with the search for and exploitation of opportunities. Besides, one could also argue that collaboration can be seen as a new kind of coordination by which to govern the entrepreneurial mode of exploitation for sustainable and societally-desirable innovation.

Critics might argue that concepts for integrating stakeholders into the entrepreneurial process already exist under the notion of open innovation (Chesbrough 2003; Hippel 2005) and that the contribution of the framework is limited. It is true that an analogy to open innovation can be drawn. Both concepts refer primarily to the way or process of how innovations are generated, rather than making an assertion on the properties of innovation itself. Moreover, both concepts strongly depend on

the internalization of external knowledge. Nevertheless, it is argued that the conceptual approach emphasizes an additional important aspect of collaboration. In comparison to open innovation, the type of information flow is broader. Open innovation is mainly related to knowledge of the technological and commercial aspects to be internalized. RI, by contrast, is also characterized by a focus on knowledge of the societal aspects of innovation. It is not just about making products or services more profitable for firms and more useful for its users, but especially about the broader influence of innovations on society. RI includes a consideration of aspects seen as crucial against the background of the sustainable development paradigm and the SDGs.

This chapter theoretically connects the two domains of RI and entrepreneurship. It provides a framework to integrate the concept of RI into the entrepreneurial process in order to promote a more sustainable and inclusive exploitation of opportunities. Therefore, the concept of responsible entrepreneurship was introduced, understood as the transformation of opportunities into innovation through entrepreneurial action moderated by collaborative reflection on normative ends of the process and its outcomes.

This chapter can be seen as a first step to building a theoretical basis for empirical studies that focus on stakeholder engagement as an instrument for collaborative reflection to promote the holistic goals of RI by examining ways to realize such an involvement in practice and its influence on the mode of exploitation. In this context, the identification of drivers and barriers to its integration plays an important role too. Due to the nature of this chapter, that is, an initial examination of the nexus of entrepreneurship and RI, there are some limitations. The definition of stakeholder engagement implies that it is already part of a wide variety of organizational activities (e.g., supply chain management, HRM, customer service, public

relations, etc.). Moreover, the definition of stakeholders shows that entrepreneurial organizations are between the poles of differing claims and demands, resulting in the question of how to handle this situation appropriately. Furthermore, an effective collaboration of the parties includes requirements that are not dealt with in detail in this chapter. Potential research questions for future research that examines the nexus of RI and entrepreneurship are noted in Table 1, clustered by the three zones of the outlined framework.

Table 1: Potential Research Questions for Future Research

Domain	**Potential research questions**
Ecosystem/Stakeholders	Who are relevant stakeholders?
	What are stakeholder's motivations, interests, expectations and needs?
	How can the network of relationships between the actors be described?
	What power structures exist and how do they influence the collaboration process?
Collaborative reflection	What are the drivers and barriers, or benefits and risks of collaboration?
	What mechanisms, rules and structures of collaboration exist?
	How can the role of the coordinating agent be managed effectively?
	What kind of knowledge is exchanged?
Process	What is the influence of stakeholders during the entrepreneurial process?
	How do different stakeholders influence this process?
	How does the set of relevant stakeholders change during the different phases?

One aspect that is essential for future research at the intersection of innovation, entrepreneurship and stakeholder theory is the role of uncertainty. It is important to understand how uncertainty about the impacts of entrepreneurial activities can be minimized to allow for more sustainable and desirable innovations. With respect to RI, Grunwald (2011) points out that responsibility "associates ethical questions regarding the justifiability of decisions in and on science and technology with the actions and decisions of concrete persons and groups and resulting accountabilities, and it is faced with the challenges posed by uncertain knowledge of the consequences of those decisions" (Grunwald 2011, p. 10). It is argued that through the implementation of the framework, collaborative reflection on the normative ends of innovation and its impacts can support the decrease of uncertainty during the entrepreneurial process. Hall et al. (2014) support such a perspective. They state that "[s]tudies on innovation have emphasized that the key role of any technology strategy is to overcome uncertainty. Organizations should thus actively seek out knowledge from various stakeholders as early as possible in the development cycle, when such feedback is most able to shape the technology for more effective diffusion" (Hall et al. 2014, p. 99). This also supports the argument to involve various actors throughout the entrepreneurial process. For future research, the role of such actors regarding the decrease of uncertainty plays a crucial role.

In addition to the research questions that are closely connected to the developed framework, further research potential, especially on the individual level and the effectuation approach to entrepreneurship, can be identified. Including individual action and the logic behind it will probably facilitate a better understanding of the decision-making process that shapes the transformation towards sustainable and societally-desirable innovation, as well as the role of personal responsibility during this process. It provides

another spectrum of research to examine the nexus of RI and entrepreneurship.

Overall, this chapter demonstrates that, in the context of RI, the search for opportunities and their exploitation should be performed for the "right" purpose, leading to desirable future situations. Considering societal and environmental impacts is thus a pivotal part of an organization's activities while developing and deploying new products and services. Awareness of such impacts is likely to foster desirable and sustainable solutions. Once an organization decides to exploit an opportunity and to build the business case that fits the needs of the exploitation strategy, the required resources should be used in light of the normative anchor points of RI. The collaborative reflection dimension is a key element that makes it possible to gain information, integrate external knowledge and provide input for the process regarding normative aspects, thus making the outcome more robust. Stakeholder engagement is one tool that stimulates such collaborative reflection.

However, there remains the question of how to operationalize and implement RI in practice. From the perspective of Grunwald (2012), this uncertainty should be seen as a great opportunity to actively engage with the subject and shape it. He particularly stresses the relevance of experiences from practice and the reflective learning of this practice to shape and design RI. Therefore, insights into operationalization strategies from entrepreneurial organizations within the field of advanced biotechnologies are presented in the following chapter.

3 RI AND DISRUPTIVE TECHNOLOGY DEVELOPMENT – INSIGHTS FROM THE DEBATE ON ADVANCED BIOTECHNOLOGY

In this chapter insights are presented from the debate on disruptive technology development, more specifically advanced biotechnology, regarding potential operationalization strategies for RI.

A look at the public debate on advanced biotechnologies (such as genetic engineering technologies and synthetic biology) in Europe suggests a societal rejection of these technologies in many countries of the European Union, especially those related to the food sector (Gaskell 2010). Thus, the concept of RI could provide businesses that are active in the field of advanced biotechnology with avenues towards developing ethical acceptable, sustainable and societally-desirable innovations. From my point of view, it is becoming increasingly important for businesses to promote the conjunction of economic and societal development early on if they want to be successful in the long run. This is especially true for emerging technologies with high market potential, such as synthetic biology. In 2012, synthetic biology had a market volume of USD 2.1 bn, climbing to USD 2.7 bn in 2013, and is expected to have a market potential of USD 11.4 bn by 2021 (BCC Research 2017) and record-breaking investments in the technology sector in Q1 2018 (SynBioBeta 3/31/2018).

Advanced biotechnology, especially synthetic biology, has featured prominently in the debate on the concept of RI (Grunwald 2011; Owen et al. 2012; Owen et al. 2013; Schomberg 2013). However, there is little literature on the role of biotechnology firms within this debate. Here insights on that issue derived from discussions and presentations at a workshop dealing with the role of advanced biotechnology (such as synthetic biology) for the

responsible operationalization of a bio-economy are presented. During the workshop, an extended workshop report was produced, which is the basis for the analysis. This inductive and qualitative approach generates in-depth insights into the topic, a deep holistic understanding of issues related to RI in an entrepreneurial context and makes it possible to build typologies of RI-related activities (Dana and Dana 2005; Dana and Dumez 2015).

3.1 Providing Space for Collaborative Reflection – A Workshop Approach

Due to its potential to generate new metabolic pathways, including ones that have no blueprint in nature (see, e.g., Yim et al. 2011; Barton et al. 2015), synthetic biology is predestined to be—and is already being—used in the processing of biomass to produce industrial goods such as biofuels, commodities for the chemical industry and ingredients for consumer goods. Given that the notion of a bio-economy is focused precisely on this kind of approach, it is clear that there is a strong connection between synthetic biology as a technology and the bio-economy as an overarching concept.

Against this backdrop, the workshop aimed to see experts from the fields of economics, technology assessment, science and technology studies, industry, private investors, civil society organizations (CSO) and policy-making discussing their perspectives on bio-economic notions, expectations and future challenges. The workshop was held under the Chatham House Rule and within the framework of the EU-funded SYNENERGENE initiative in Brussels in 2015.

3.2 Entrepreneurial Perspectives on the Operationalization of RI in the Advanced Biotechnology Field

With regard to the responsible operationalization of a bio-economy, the perspectives of industry representatives on the role of advanced biotechnologies (and synthetic biology in particular) have particular relevance to this study. Therefore, four presentations (P1-P4) delivered at the workshop are analyzed in relation to the extended workshop report. In the following section, the statements related to the concept of RI are emphasized.

The first presentation (P1), delivered by a top management representative of a biotechnology industry association, emphasized the need for an open and transparent dialogue around the development of the bio-economy as a key measure to ensure a competitive and sustainable EU bio-economy.

A mid-level manager of a large biotechnology company delivered the second presentation (P2), focusing on the company's open innovation approach. Citing the European Union's open innovation concept as described by the European Commissioner for Research, Science and Innovation, Carlos Moedas, open innovation was described as "involving far more actors in the innovation process, from researchers to entrepreneurs, users, governments and civil society" (European Commission 6/22/2015). Open innovation was characterized as an opportunity for companies to get "ready for disruption" by engaging with external communities or stakeholders (e.g., do-it-yourself (DIY) biotech/biohacker communities). Such involvement and engagement might be mutually beneficial to both sides. On the company side, this could include elements such as the development of new technologies, spotting next big trends in biotechnology, or talent scouting. Conversely, mentoring and sparring with experienced scientists, validation and feedback on

technologies and projects, or relationship building with businesses were mentioned as benefits for external communities or stakeholders.

The perspectives of representatives from two small- and medium-sized enterprises (SMEs) that applied synthetic biology to produce goods supplemented these two presentations. The third speaker (P3), a representative from an SME's top management, talked about the company's activities to foster RI. The main ones were: complying with the United Nations Convention on Biological Diversity's Nagoya Protocol; working in a number of pilot programs to implement RI in the R&D process; promoting transparency (e.g., on the company homepage); public engagement (also meeting critics); supporting biodiversity (e.g., 1% of revenue went to biodiversity conservation and education activities in poor countries); and providing independent lifecycle or sustainability assessments.

The fourth presentation (P4) was delivered by a mid-level manager of an SME, who emphasized lessons learned from the debate on synthetic biology. Important lessons were to explain and lead with a mission ("why it matters"); to show independent verification of claims, such as data based on international standards; being aware of the social dimension of sustainability; and engaging with stakeholders and critics. These points were put into the context of a list of the company's commitments towards RI, which are transparency and the highest safety standards regarding processes, technology and products; dialogue and engagement with stakeholders; and support of communities in which the company operates.

Table 2 contains a summary of the key statements of the presentations that are related to the concept of RI. Whereas the first presentation had only an implicit link to the concept of RI, the other speakers (P2, P3, P4) presented concrete activities to foster RI as an integral part of their strategy and a valuable goal they aimed for.

Table 2: Statements related to the Concept of RI

Speaker	Statements
P1 – representative of a biotechnology industry association (top management)	Open and transparent dialogue around the development of the bio-economy, as well as the technologies driving the bio-economy (advanced biotechnology/synthetic biology)
P2 – representative of a large biotechnology company (mid-level management)	Exchange with stakeholders through an open innovation approach with mutual benefits
P3 – representative of an SME that applies synthetic biology (top management)	Complying with the United Nations Convention on Biological Diversity's Nagoya Protocol; pilot programs to implement RI in the R&D process; transparency; public engagement (also meeting critics); supporting biodiversity (e.g. 1% of revenue went to biodiversity conservation and education activities in poor countries); providing independent life cycle/sustainability assessment
P4 – representative of an SME that applies synthetic biology (mid-level management)	Transparency and highest safety standards regarding processes, technology and products; dialogue and engagement with stakeholders; support of communities in which the company operates; showing independent verification of claims

The activities ranged from compliance in terms of philanthropic activities to approaches that might lead to the co-creation of products or technologies. In a broader sense, one could argue that the activities ranged from informative to more interactive approaches. The activities named by the industry representatives can be grouped into four clusters with differing levels of interaction (listed by decreasing level of interaction):

a) *Stakeholder engagement and public dialogue* (e.g., through an open innovation approach with mutual benefits, or by meeting critics)
b) *Philanthropy* (e.g., supporting biodiversity initiatives or local communities)

c) *Openness, transparency and validation of benefits* (e.g., regarding processes, technology and products, or the independent verification of claims/independent lifecycle/sustainability assessment)
d) *Compliance* (e.g., with the United Nations Convention on Biological Diversity's Nagoya Protocol, or applying safety standards)

It becomes clear that there is a strong focus on collaboration, which is one of the core dimensions of RI described above. The representatives see the need for mutual exchange and stakeholder engagement, but also demand that other actors be willing to collaborate. All four presentations contained elements that might be essential to shaping advanced biotechnology in a responsible manner. However, it is still unclear how or to what extent the opposing views of stakeholders (such as CSOs) can be integrated in practice.

3.3 Discussion

Considering collaboration as a dimension of RI is not only supported by the literature (as described in section 2.3.2), but also by the industry perspectives presented at the workshop. All the representatives had a strong focus on collaboration. They saw the need for mutual exchange and stakeholder engagement. This point of view was also held by other stakeholders who took part in the workshop. As a general conclusion of the workshop, it can be stated that, as a prerequisite for such an endeavor, "responsible" would also have to mean being responsive to societal needs, demands and/or values. Since needs and values might differ between stakeholders, (co-)responsiveness to differing needs and values would require inclusive processes - including all stakeholders and potentially impacted people - and, at some point, would have to result in mutual obligations. Thus, in order to collaborate, a common view was that it would be essential to bring different notions and views together. This would

require platforms for the (continuous) engagement of stakeholders and the public in order to foster exchange and debate.

Importantly for such inclusive processes, “responsible” was also broadly seen to mean being honest and transparent about promises and challenges. This would also include becoming aware of limits and acknowledging limitations. However, although there was a common understanding that an inclusive process and mutual exchange was vital, the question of how to reach this goal was left unanswered.

Even though it is yet unclear how to reach this goal, there might be a major driver for such an endeavor in disruptive technology development processes. The past has shown that especially products based on emerging technologies, with which people are not familiar and/or that they feel uneasy about have not been accepted (e.g., GMOs in food). Similarly, some CSOs, including ETC Group Friends of the Earth and the Heinrich Böll Foundation, have a highly critical attitude to emerging technologies such as synthetic biology (ETC Group 2010; ETC Group and Heinrich Böll Foundation 2015a, 2015b; Friends of the Earth 2010). This could be one reason for which the speakers from the two SMEs that apply synthetic biology emphasized the important role of RI for their business. This controversy could become even more intense because the focus of applications of synthetic biology is changing. Whereas so far the focus has been primarily on the development of production methods for biofuels and commodities, various businesses are striving for high value products in the food and personal care sector, and in the cosmetics industry (Check Hayden 2014). A better understanding of the needs and concerns of society could help companies to avoid throwbacks that could result in a negative image, or even in the loss of the “social license to operate.” It is not only organizations dealing with emerging technologies that could benefit from such an approach. Integrating the principles of RI into the entrepreneurial

process might lead to a better understanding of needs and concerns, and might enable innovators to engage with society in order to gain new ideas and knowledge, and thus reduce uncertainty connected with the search and exploitation of opportunities.

The insights from the debate on advanced biotechnologies presented have to be considered in light of some limitations. First, the analysis is based on an extensive but summarized workshop report; no primary data, such as audio recordings, are available. Secondly, the statements of the industry representatives were not verified by triangulation or other methods. Nonetheless, they indicate vital issues that are being addressed and are seen as important by entrepreneurial organizations related to operationalizing RI. Furthermore, as advanced biotechnology can be seen as a disruptive technology, these statements might serve as starting points to follow the development of this debate in the future. Finally, the insights presented are valuable because such data is difficult to access. One could argue that the insights were presented by representatives of SMEs, an industry association and a large company, and hence have only a minor link to entrepreneurship. However, apart from the fact that entrepreneurship can also take place within SMEs or large corporations (intrapreneurship; see, e.g., Rule and Irwin 1988; Knight 1987; Ratten 2012; Gaertner 2015), entrepreneurship is characteristic of the advanced biotechnology sector in general. Hence the insights presented help us to learn how entrepreneurial organizations deal with RI and to discern avenues towards its operationalization.

PART 2

4 THE ROLE OF STAKEHOLDERS IN DISRUPTIVE TECHNOLOGY DEVELOPMENT PROCESSES

In this chapter, the focus is on the role of stakeholders in RI. The exposition is located at the intersection of stakeholder theory, entrepreneurship and innovation. Using a qualitative research approach, the role of stakeholders is examined in relation to the uncertainty of entrepreneurial processes. By reviewing the literature, the relevance of the RI approach to entrepreneurial organizations active in the field of disruptive technology development and the reduction of uncertainty as a core driver of stakeholder engagement activities are identified. The goal is to understand which stakeholders in entrepreneurial organizations engaged in disruptive technology development contribute to the reduction of uncertainties in the four areas of uncertainty—technological, commercial, social and organizational—identified by Hall et al. (2014) and Hall and Martin (2005). An analysis of in-depth interviews with representatives who were holding key positions at nine SMEs and start-ups active in the field of advanced biotechnology generated insights into the role of various stakeholders on the reduction of uncertainty. The findings indicate that stakeholder engagement plays a crucial role in the reduction of uncertainty. In addition, the analysis highlights the need to focus on indirect stakeholders in disruptive technology development processes to reduce social uncertainty, because such technologies might have controversial and widespread social and environmental consequences.

4.1 Theoretical Background

4.1.1 RI and Stakeholder Management

The premise of RI, namely that innovators and other actors within society should collaborate to make products and services more societally-desirable and sustainable, can be operationalized by opening up the process to the entrepreneurial firm's ecosystem. Isenberg (2011) defines six domains of the entrepreneurship ecosystem: policy, finance, culture, supports, human capital and markets. Every single domain is represented by actors who operate within this domain. These actors can be referred to as stakeholders, which are groups or individuals that "can affect or are affected by the achievement of the organization's objectives" (Freeman 1984, p. 46). This definition emphasizes the multidirectional interdependencies between the entrepreneurial organization and its ecosystem. Thus, there is a shift from the conventional input-output perspective, in which actors are depicted as contributors of input that is transformed into outputs by the firm, towards a two-way relationship perspective in which the firm's actions also affect these actors (Donaldson and Preston 1995).

There are various theoretical perspectives on stakeholder management theory. Donaldson and Preston (1995) distinguish between descriptive, instrumental, and normative approaches with respect to two-way stakeholder relations. The descriptive approach describes and explores corporate characteristics that drive stakeholder relations. The instrumental perspective deals mainly with the connections between the practice of stakeholder management and its outcomes in terms of various performance goals, such as profitability, growth, social performance or innovation. The basis for the latter two approaches is the normative perspective, in terms of which stakeholders are seen as groups or individuals who have a legitimate

interest in the processes and products of the firm, or are part of an environment whose interests need to be considered.

There are several approaches to differentiating stakeholder categories, such as normative and derivative stakeholders (Phillips 2003; Phillips et al. 2003) or primary and secondary stakeholders (Freeman 1984). Whereas normative stakeholders are those to whom the organization has a direct moral obligation (e.g., financiers, employees, customers, suppliers or local communities), derivative stakeholders are groups or individuals to whom the organization has no direct moral obligation, but who could harm or benefit the organization as stakeholders (e.g., competitors, activists, terrorists and the media). In contrast, primary stakeholder are groups or individuals who have a direct impact on the firm. Secondary stakeholders do not directly interact with the organization but might indirectly influence it. This primary/secondary stakeholder perspective of Freeman was narrowed down by Clarkson (1995). He defined primary stakeholders as those whom the organization needs to survive (e.g., shareholders, investors, employees, customers, suppliers, governments and communities) and secondary stakeholders as those who are not essential for its survival and are not engaged in transactions with the organization, but who can influence, affect or be influenced or affected by the organization (e.g., media and special interest groups).

Both approaches have the same or similar examples for their categories of stakeholders, which shows that there is a common perspective on how to categorize stakeholders. However, the two approaches differ in their description of the relationship between the organization and its stakeholders. The normative/derivative stakeholder perspective is about the obligations the organization has to the stakeholders and thus represents mainly an output dimension (from the organizations towards the stakeholders). In contrast, the primary/secondary perspective depicts

stakeholders mainly as a resource for the organization and thus represents an input dimension (from the stakeholders towards the organization). It is argued that both perspectives are necessary to describe the two-way relationship approach of Donaldson and Preston (1995) described above. Both perspectives are crucial in the context of RI. On the one hand, stakeholders should provide input for the organization that makes it possible to align products and services with societal needs and expectations and, on the other hand, the effects or impacts of the organization's activities on stakeholders should be considered.

To take these multidirectional interdependencies between the entrepreneurial organization and its ecosystem into account, it is necessary to differentiate between the supercategories, namely direct and indirect stakeholders, who are defined by their involvement in the organization's activities. Direct stakeholders are those who are directly involved in the processes of organizations (e.g., investors, advisors) and indirect stakeholders are those who are only indirectly involved in these processes (e.g., NGOs, media). Nevertheless, in such a categorization there are no exclusive poles, but rather a continuum. There are some stakeholder groups that do not necessarily fit one or the other category (see Figure 5).

In this model there is a high level of direct interdependence between the organization and its direct stakeholder groups that can support or impair its activities. Even though there are no direct interdependencies between the organization and its indirect stakeholders, they can influence its activities, both in a positive or negative manner. Similarly to the primary/secondary stakeholder perspective (Freeman 1984), such groups can cause significant damage to an organization; for example, they could mobilize public opinion in favor of, or in opposition to, an organization's performance and thus influence the organization by manipulating direct stakeholders (Clarkson 1995). The normative/derivative stakeholder perspective (Phillips 2003;

Phillips et al. 2003) also requires such groups to be taken into account during decision making, because they might influence the organization or other stakeholders (Phillips et al. 2003). Hence, an organization should also be managed for the benefit of indirect stakeholders and they should be taken into account during decision-making processes.

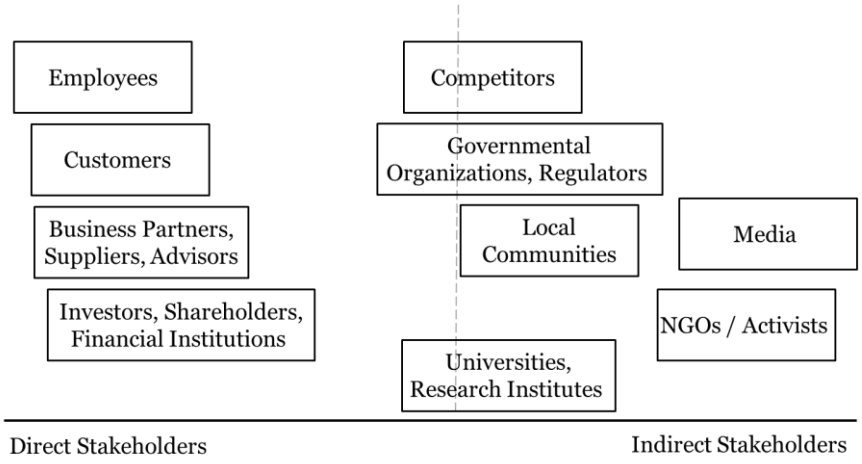


Figure 5: Exemplary Range of Stakeholders (based on Hall and Martin 2005)

Whatever the categorization, there are several benefits of stakeholder management. One is that firms that create and sustain stakeholder relations on the basis of mutual trust and cooperation would have a competitive advantage over those that do not (Barney and Hansen 1994; Hart and Sharma 2004; Jones 1995). This goes hand in hand with the argument of Post et al. (2002), who assert that the management of "critical" stakeholder relations is a potential core competence for management and that it can involve stakeholders from all categories. Effective stakeholder management, in the sense of a holistic approach in which the effects of decisions regarding resource allocations are considered *vis-a-vis* key stakeholders, is key to gaining competitive advantage for firms whose thinking is more atomistic (Berman et al. 1999).

4.1.2 Stakeholder Management and Disruptive Technology Development

The importance of stakeholder analysis has also been explicitly recognized in technology development. In this field, there is a variance in interests and perspectives among the stakeholders involved (Tipping et al. 1995; Crane and Ruebottom 2011). This is also true of indirect stakeholders (Elias et al. 2002), because new technologies affect different stakeholders in different ways. Especially for entrepreneurial organizations involved in disruptive technology development stakeholder analysis is crucial as this new technology might have widespread social and environmental implications that could be controversial (Ashton 1948; Freeman and Soete 1997; Hall and Martin 2005).

Because of such potential wide-ranging social and environmental implications, disruptive technology development is often affected or influenced by both direct and indirect stakeholders. In this context, Hall and Martin (2005) identified a research gap in the literature. They argued that the focus was on direct stakeholders, while the role of indirect stakeholders was neglected, even though they were playing an increasingly important role in business activities (Hall and Vredenburg 2003; Porter and Kramer 2011; Waddock et al. 2002). Furthermore, they argued that the ability to accommodate pressures from different stakeholder groups was a key challenge in disruptive technology development to exploit potential benefits as well as assess, manage and minimize the unforeseen, unintended negative consequences.

In general, stakeholder engagement can be defined as “practices that an organization undertakes to involve stakeholders in organizational activities in a positive way” (Greenwood 2007), which can provide access to information or resources (Hart and Sharma 2004; Street and Cameron

2007), stimulate mutual understanding (Gao and Zhang 2006), and promote collaboration and shared objectives among stakeholders (Andriof and Waddock 2002).

4.1.3 Innovation and Uncertainty

On the one hand, uncertainty can be seen as a necessary condition for entrepreneurship and the implementation of innovation (Foster 2010; York and Venkataraman 2010). With regard to the fact that one of the core assumptions in entrepreneurship research is the notion that entrepreneurs make decisions and act in the face of uncertain or unknowable futures (e.g., Sarasvathy et al. 2005; Knight 1921; Shane and Eckhardt 2005), McKelvie et al. (2011) state that "[e]ntrepreneurship is a process that involves some degree of uncertainty, and thus the ability of entrepreneurs to interpret and respond to uncertainty is often what determines the degree of success or failure achieved by the venture" (McKelvie et al. 2011, p. 273). McMullen and Shepherd (2006) similarly suggest that entrepreneurship requires a judgment about action that takes place over time in the face of an unknowable future. Thus it should be no surprise that "uncertainty constitutes a conceptual cornerstone for most theories of the entrepreneur" (McMullen and Shepherd 2006, p. 132).

On the other hand uncertainty is also an obstacle that needs to be overcome during the entrepreneurial process to establish innovation (Hall et al. 2014). This is especially true when disruptive technologies are applied, because they cause technological change that "requires the transition from one technology paradigm to another and, therefore, is not only less likely to occur but is also associated with higher uncertainty than innovation along a given trajectory" (Dosi 1982). Such transitions are often connected with highly dynamic business environments in which the frequency of change is high and the outcomes of these changes are unpredictable or unknowable

beforehand (e.g. Eisenhardt and Martin 2000). Such transitions are accompanied by the necessity for organizations to have the ability to assess possible future developments, and identify and decrease uncertainty in order to successfully establish innovations.

One of the earliest definitions of uncertainty was provided by Knight (1921). He distinguished between "risk," defined as a measurable unknown to which probabilities can be assigned, and which can be dealt with by means of insurance, and "uncertainty," to which one cannot assign probabilities or predict in an accurate way. Since then the popularity of the topic of uncertainty has increased immensely and it is often referred to as "the Knightian understanding of uncertainty." However, despite the popularity of the topic, there is no agreement about the conceptualization of the concept (McKelvie et al. 2011). According to Jalonen (2012), Galbraith (1977) "has ironically stated that 'a great deal of uncertainty exists about the concept of uncertainty'" (Jalonen 2012, p. 5). Scholars widely acknowledge the important role of uncertainty, especially in entrepreneurship research, but there is no shared notion of exactly how to conceptualize it (McKelvie et al. 2011). McKelvie et al. (2011) see one reason for this lack of consensus about uncertainty in entrepreneurship research as the fact that entrepreneurial environments are often described as risky, ambiguous, dynamic and turbulent by practitioners and scholars, who often imply that these terms are synonymous with uncertainty (Shane 2007; Lipshitz and Strauss 1997). Furthermore, McKelvie et al. (2011) demonstrate this ambiguity by giving examples of different conceptualizations of uncertainty. They state that "[s]ome suggest that uncertainty refers to the 'inability to assign probabilities to the likelihood of future events' (Duncan 1972; Pennings 1981; Pfeffer and Salancik 1978), while others define uncertainty as 'a lack of information about cause–effect relationships' (Lawrence and Lorsch 1967) [… and s]till others have suggested that uncertainty describes, 'an inability to predict accurately what the outcomes of a decision might be'

(Downey et al. 1975; Duncan 1972; Schmidt and Cummings 1976)" (McKelvie et al. 2011, p. 276). Although there is no commonly agreed upon concept of uncertainty in the literature, in a general manner uncertainty can be understood as a lack of knowledge about the state of the future which is caused by insufficient information. One might argue that there is a gap between the required information to make decisions and the already acquired information. Understanding uncertainty as a situation in which a lack of information is present also implies that uncertainty can be reduced by acquiring additional information (Daft and Lengel 1986; Galbraith 1977; van Riel et al. 2004).

With regard to entrepreneurship, McKelvie et al. (2011) conclude that uncertainty is a prominent notion in entrepreneurship discourse, but the influence of this notion on the entrepreneurial process is ambiguous. They state that "we actually understand very little about how and under what conditions uncertainty may influence important outcomes in entrepreneurship" (McKelvie et al. 2011, p. 274). This also means that there is little knowledge about how information is gained throughout the steps and stages of the entrepreneurial process to reduce uncertainty, or about which stakeholders could play a role here.

It becomes evident that uncertainty reduction is a key competence for innovating organizations engaged in disruptive technology development. In this context, Hall et al. (2014) state that "[o]rganizations should thus actively seek out knowledge from various stakeholders as early as possible in the development cycle, when such feedback is most able to shape the technology" (Hall et al. 2014, p. 99). Hence, stakeholders can be seen as a source of knowledge and information that can help to reduce uncertainty.

4.2 Research Approach

Against this backdrop, an attempt was made to determine which stakeholders of entrepreneurial organizations engaged in disruptive technology development contributed to the reduction of uncertainties and how this occurred. Therefore, the supercategories of stakeholders outlined above were used:

- Direct stakeholders: employees, customers, partners, suppliers, advisors, investors, shareholders and financial institutions
- Indirect stakeholders: competitors, governmental organizations, regulators, local communities, universities, research institutions, media, NGOs and activists

With regard to uncertainty, the four categories described by the research group around Jeremy Hall (Hall et al. 2011; Hall and Vredenburg 2003; Hall et al. 2014; Hall and Martin 2005) were utilized, because they focus on new and radical technologies. They suggest that an organization must overcome four categories of uncertainty to successfully establish disruptive innovation. These four categories are named and defined as follows:

a) Technological uncertainty concerns overcoming scientific, technical and engineering hurdles
b) Commercial uncertainty is about whether the new technology can compete successfully in the marketplace
c) Social uncertainty concerns the societal impact on or by society, legitimization and acceptance of the technology
d) Organizational uncertainty is about whether an organization is able to capture the benefits of the technology

In order to identify the experience and opinions of thought leaders from organizations active in disruptive technology development regarding the influence of various stakeholders on uncertainty, an exploratory and

qualitative approach was adopted for this study. This made it possible to generate in-depth insights on and a deep holistic understanding of the topic (Dana and Dana 2005; Dana and Dumez 2015). Such an approach affords participants the opportunity to share their experience and pass on their knowledge (Boeije 2009). Bryman (2016, p. 470) states that "in qualitative research, there is an emphasis on greater generality in the formulation of initial research ideas and on the interviewees' own perspectives." Due to the exploratory character of this study, the interviewer had to cover a lot of ground and had to utilize the flexibility of a qualitative, semi-structured interview approach. "In qualitative interviewing, interviewers can depart significantly from any schedule or guide that is being used. They can ask new questions that follow up interviewees' replies and can vary the order and even the wording of the questions [...] as a result, qualitative interviewing tends to be flexible, responding to the direction in which interviewees take the interview and perhaps adjusting the emphases in the research as a result of significant issues that emerge in the course of the interviews" (Bryman 2016, p. 470). This aspect of qualitative semi-structured interviews, that is, being able to anticipate and change the questions, made this method the perfect fit for this exploratory research. Hence, semi-structured interviews with CEOs, founders and top-level managers of advanced biotechnology medium-sized enterprises (SMEs) and start-ups were conducted (see Annex I for the interview guidelines).

Nine interviews were conducted with interviewees located in three different countries. At the time, the interviewees were holding key positions at nine different SMEs or start-ups active in the field of advanced biotechnology. To ensure anonymity, the names of the interviewees and their companies cannot be identified. Therefore, an overview of the interviewees' characteristics is provided in Table 3 (see Annex II for the declaration of anonymization).

Table 3: Overview of Interviewee Details

Headquarters based in	6 x United States, 2x United Kingdom, 1x Switzerland
Types of Businesses	Advanced Biotechnology / Synthetic Biology
Sizes of Businesses	3 x Start-Ups, 6 x SMEs
Positions held	4 x CEO/Founder, 1 x President, 4 x SVP/VP

The company database of SynBioBeta was used to identify firms and start-ups active in the field of advanced biotechnology. SynBioBeta is a hub for the synthetic biology industry. The scope was further narrowed down by using the categories of "food applications" and "consumer products, personal care, fragrances" given by the database. Additionally, personal contacts from the SYNENERGENE project were used. This focus was chosen due to the high uncertainty in the areas of food applications and consumer products, personal care and fragrances. Most firms active in these areas explore new fields and thus cannot build upon previous experiences or use other firms as role models. Due to its high level of innovativeness and uncertainty (Schoonmaker et al. 2017), the advanced biotechnology sector, with a focus on the areas mentioned above, was seen as an excellent fit for this study. With respect to the concept of "information power" (Malterud et al. 2015), the interview sample size was sufficient for the scope of this qualitative study. To test the clarity of the questions, the design of the interview guideline and the interview conditions (Häder 2010), a pre-test interview with a senior biotechnology manager was conducted. After the test interview, the test candidate was asked to comment on the questions and the interview process, which led to minor adaptions of the overall interview design.

The interviews, which were conducted via Skype to Skype and Skype to phone, were recorded by mutual agreement using Amolto Call Recorder for Skype (Version 3) and afterwards transcribed by a professional transcription service, which applied intelligent *verbatim* transcription rules. The analysis of the transcripts was undertaken centrally to ensure consistency. The analysis was supported by the use of MAXQDA qualitative data analysis software (Version 12). For the manuscript, the quotations were edited by the author to enhance clarity and readability, and to ensure anonymity, while fully maintaining the meaning and tone of the quotations.

4.3 Findings and Discussion

Before exploring the influence of a variety of stakeholders on the different areas of uncertainty, the general role of stakeholder engagement for the interviewed firms is described to emphasize the general characteristics and importance of such engagement activities. Table 4 at the end of the chapter shows significant quotations of the interviewees while talking about benefits of and motivations for stakeholder engagement.

It was evident that the main benefit of stakeholder engagement for firms active in advanced biotechnology was the exchange of information. Most of the interviewees directly or indirectly referred to the importance of acquiring information from stakeholders to inform strategy, to make the right assumptions and ultimately to increase performance. Some of the interviewees also emphasized the importance of gaining such information at an early stage, which supports Hall et al.'s (2014) assertion that the early acquisition of information is important because it is then most able to help shape technology for more effective diffusion.

The identification of information exchange as the main objective of engagement with stakeholders implies a link to the reduction of uncertainty.

Some of the quotations illustrate this connection superbly. For example, "[…] getting feedback early on, [… to] inform what our strategy would be" (Interview 2) and "to prevent surprises" (Interview 5). Thus, stakeholder engagement is seen as an effective way to acquire information and reduce uncertainty. To gain a better understanding of which stakeholders play a role in the reduction of uncertainty in the areas identified by Hall et al. (2014) and Hall and Martin (2005), the interviewees were asked if there were stakeholders that helped to:

a) overcome scientific, technical and engineering hurdles (technological uncertainty)
b) evaluate commercial feasibility (commercial uncertainty)
c) assess social and environmental impacts (social uncertainty)
d) capture the benefits of the technology (organizational uncertainty)

Significant quotations regarding the different areas of uncertainty are listed in Table 5 at the end of the chapter.

With respect to the roles of the stakeholders in reducing technological uncertainty, the interviewees indicated that direct stakeholders played a significant role. Employees and advisors in particular were seen as knowledge carriers who could assist in overcoming scientific, technical and engineering hurdles. Six out of the nine quotations mention employees as important stakeholders. Three even refer exclusively to employees as stakeholders who help to reduce technological uncertainty (Interview 3, 5 & 9) and a fourth quotation refers mainly to employees in this regard (Interview 1). In this context, it is worth emphasizing one specific comment that was made by the founder and CEO of one of the start-ups:

> "Besides the employees, I don't think other stakeholders have had a big influence on our technology platform" (Interview 9).

The above quotation aptly summarizes the importance of employees with respect to coping with technological uncertainty. Nevertheless suppliers, academic researchers and associations also play a role in reducing technological uncertainty by providing access to information. For example, technical experts at suppliers provide input to solve technical problems and academic researchers help to address scientific challenges (Interview 6).

With respect to commercial uncertainty, the categories of stakeholders involved in its reduction are more diverse than those in the area of technological uncertainty. Nearly every interviewee referred to different stakeholders. The latter included associations, customers, advisors, employees and investors. This diversity of responses was also rather extreme. One participant said that all stakeholders played an important role because they all provided useful information regarding commercial uncertainty (Interview 1), whereas another one argued that stakeholders did not help at all because they focused exclusively on the reasons for which the venture would fail. Nevertheless, the president of R&D of one of the SMEs emphasized the importance and the role of customers for the biotechnology industry:

> "That's usually done in collaboration with the customer. Everything we've introduced is intended to be a replacement for an existing incumbent. So they already have a good idea of what the price of the product they're buying is and what price they would like to buy that" (Interview 5).

Firms in the field of biotechnology often operate in a business-to-business setting and develop very specific components for their customers. The following quotation encapsulates this in an extremely precise way. Although the types of stakeholders were diverse in relation to commercial uncertainty, the participants referred mainly to the supercategory of direct stakeholders.

In the area of social uncertainty, the categories of involved stakeholders were also diverse. Nevertheless, it was mainly stakeholders from the supercategory of indirect stakeholders that were seen to support the reduction of social uncertainty by helping to companies to assess social and environmental impacts. In this context, two quotation stand out because they are most significant with regard to social uncertainty:

> "Regarding social and environmental impacts, we get the best feedback and the most useful and important feedback absolutely from the non-profit community, from social and environmental activists" (Interview 8).

> "Engaging with some non-profits have definitely made us think about: How can we be better at sourcing? How can we make it both economical and ethical? And I think from that perspective it's a very important point to consider" (Interview 1).

NGOs obviously play an extremely important role in the reduction of social uncertainty for biotechnology firms. Another category that helps organizations to directly asses social and environmental impacts is research institutions. This is reflected in two of the quotations (Interview 2 & 3), in which the interviewees directly refer to research institutions. Interviewee 3, for example, referred to an organization that does a lifecycle analysis to quantify water, energy and land usage, as well as greenhouse gas emissions. The fact that indirect stakeholders play a key role in the reduction of social uncertainty fits very well with the assertions of Hall and Martin (2005). They suggest that there is a need to also focus on indirect stakeholders to reduce social uncertainty. This plays an important role when it comes to disruptive technologies - in this study advanced biotechnology - because such technologies might have widespread social and environmental

implications that could be controversial (see section on stakeholder management and DTD).

Most of the interviewees struggled with the question concerning the role of stakeholders regarding organizational uncertainty. In retrospect, this might have been due to the nature of the question, because most of the interviewees might have perceived organizational uncertainty - the ability to capture the benefits of the technology - too mean internal uncertainty. However, this is only a possible explanation for the struggles with the question and the few significant quotations in this area. When asked about how stakeholders helped to capture the benefits of the technology, the participants mentioned stakeholders from both supercategories, such as local communities, associations, the media and customers. Due to the little available data in this area of uncertainty, it does not make sense to prioritize one of the two supercategories, because there were neither a significant number of indications nor any significant quotations from the interviewees regarding this issue.

4.4 Discussion

The study contributes to the discussion on the role played by stakeholders during the entrepreneurial process, especially in terms of their contribution to the reduction of uncertainty in DTD and the role of indirect stakeholders. By conducting nine in-depth interviews with representatives from nine different firms involved in disruptive technology development, namely advanced biotechnology/synthetic biology, one can conclude that

a) Stakeholder engagement reduces uncertainty
b) It is mainly direct stakeholders who help to reduce technological uncertainty
c) It is mainly direct stakeholders who help to reduce commercial uncertainty

d) It is mainly indirect stakeholders who help to reduce social uncertainty

The analysis indicates that the interviewees saw a strong connection between the engagement of stakeholders and the reduction of uncertainty. It becomes evident that the main benefit of stakeholder engagement for firms active in advanced biotechnology is the exchange of information. Most of the quotations directly or indirectly refer to the importance of acquiring information from stakeholders to inform strategy, facilitate making the right assumptions and ultimately increasing performance. Stakeholder engagement is, therefore, an effective way to acquire information and reduce uncertainty.

With regard to the different areas of uncertainty, the interviewees indicated that, with respect to technological uncertainty, the most important stakeholders who helped to overcome scientific, technical, and engineering hurdles were direct stakeholders, especially employees and advisors.

In comparison, with respect to commercial uncertainty, the categories of stakeholders involved in its reduction were more diverse. Nearly every quotation refers to different stakeholders. Even though the types of stakeholders are extremely diverse, the quotations also mainly refer to direct stakeholders who play a role in the reduction of commercial uncertainty.

In the area of social uncertainty, the categories of involved stakeholders are also relatively divers. Nevertheless, it is mainly stakeholders from the supercategory of indirect stakeholders that support the reduction of social uncertainty by helping to assess social and environmental impacts. With regard to two significant quotes, NGOs play an extremely important role in the reduction of social uncertainty for biotechnology firms. Another

grouping that helps to directly asses social and environmental impacts and reduce uncertainty in this area is research institutions.

Regarding organizational uncertainty, only few quotations were found during the analysis, but stakeholders from both supercategories were named. Due to the little available data in this area of uncertainty, it does not make sense to prioritize one of the two supercategories, because there are an insignificant number of indications and no significant quotations from the interviewees.

The study shows that stakeholder engagement plays a crucial role in the reduction of uncertainty in DTD. In addition, the findings support the assertions of Hall and Martin (2005), who suggest that there is a need to focus on indirect stakeholders in DTD to reduce social uncertainty, because such technologies might have controversial and widespread social and environmental consequences. Hence, it is important for entrepreneurs and entrepreneurial organizations to engage with such stakeholders as early as possible to gain insights that can inform their strategy and help them to reduce uncertainty along the entrepreneurial process. This can happen through stakeholder engagement methods such as focus groups, workshops, or other (regular) exchange activities. Such activities can help, especially with regard to the assessment of social and environmental impacts, to reduce uncertainty in DTD processes. However, stakeholder engagement also has some limitations. For example, a wider stakeholder analysis is connected with challenges such as high complexity and ambiguity (Hall and Vredenburg 2003; Hall et al. 2014; Hall and Martin 2005). Also, the absorptive capacity to assimilate the information gained through stakeholder engagement activities to reduce uncertainty is challenging and connected with transaction costs (Cohen and Levinthal 1990; Jones 1995; Zahra and George 2002).

Nevertheless, the study shows that RI, with its premise that it is vital to collaboratively engage during the design process of innovation, is a concept which is worthwhile pursuing, especially for organizations working on disruptive technologies, because it grants facilitates the acquisition of information to reduce uncertainty through exchange activities. RI is also a desirable approach for stakeholders. According to Dew and Sarasvathy, stakeholder engagement in the entrepreneurial process represents a "[v]oice in the (re)design of innovations [that] gives stakeholders some control over the uncertain consequences (of innovations) that get introduced in the world and is therefore valuable, particularly before the consequences are clear and predictable" (Dew and Sarasvathy 2007, pp. 275–276).

In general, the study contributes to research at the intersection of stakeholder theory, entrepreneurship and innovation; or, more generally, of technology and innovation studies and management, which is a critical area to examine (Linton and Solomon 2017; Solomon and Linton 2016). Nevertheless, the study also has limitations. As the nine interviewees held key positions in SMEs and start-ups active in the field of advanced biotechnology (at the time of the interviews), the findings should not be generalized to any populations of firms. However, the findings will hopefully encourage researchers to examine whether the results of the analysis can be generalized. Thus, the results could be used to formulate hypotheses, which can be tested by means of a quantitative approach, such as structural equation modelling. In addition, the study also shows that there is much potential for future research regarding the role of stakeholders in uncertainty reduction during the entrepreneurial process; for example, by asking in which phases of the process the different stakeholders are relevant to the reduction of uncertainty. Furthermore, future researchers could explore different fields and different firm sizes, or could perform comparative studies. The current study constitutes a useful starting point

for exploring the interface between stakeholder theory and uncertainty in the fields of entrepreneurship and innovation. It can give direction to this research area, which as relevant to academics as it is to practitioners.

Table 4:

Significant Quotations regarding Benefits of and Motivations for Stakeholder Engagement

Interview Number	Significant Quotations
1	The main benefit is information exchange: to be able to learn from them what we don't know and to share with them what they don't know about us and what we do and why we do it. It creates a communication channel that can then be expanded upon. I think there is a lot of value to be able to have an open communication channel, for example if there is a controversy or misinformation.
2	The benefits are really getting feedback early on, essentially kind of putting your finger in the water and gauging the temperature: Are people excited about this? What are the feelings out there? To help kind of inform what our strategy would be. And also I think one of the benefits of engaging with stakeholders early on is understanding what we have to think through before commercializing.
3	It's a little bit like saying: Why do you breathe air? I mean that's what we are here for. I mean, you know, we are here to engage with people and we are here to offer them a solution.
5	Well, I think the main benefit is to prevent surprises. I think where businesses go wrong is when you make assumptions about how quickly a product will be taken up by the market place, how much resistance there will be from the public. All those things are really important. There you have a good understanding, so that you can make informed decisions about what kind of products to deploy.
6	Now why we do that is because if we didn't we would find ourselves investing a lot of money and a lot of time and a lot of effort to something that in the end doesn't solve the problem for anyone. There is always a two-way exchange that gives us access to information that makes us go faster, improves the probability of success or reduces the uncertainty the way the market is going to react to the change that we're trying to enable. If we can generate an impact, we can make a return. But we don't know if it's going to have an impact unless we engage with our stakeholders.
7	Biotechnology companies that don't engage with stakeholders are more likely to find that they've developed products and there is no market for them at the end of the day. So it's important to have these conversations often.
8	We are bringing a new product to the world; so a benefit for us is to hear what peoples' questions are and what they want to know and then being able to provide that information and letting them try our products firsthand. So it's absolutely, basically, hearing from them about what they want to know and then being able to provide that information to them. So that's most important.

9	It was kind of a strategic decision we made, being open that would drive awareness, trust and sales rather than being secretive and then losing trust and interest. We have conversations with a lot of stakeholders. We had actually really high engagements from our clients. But we've also picked up the phone and talked to a lot of people and trying to understand exactly: What are their interests in the product and the platform? So that's been very important and very helpful for us.

Table 5:

Significant Quotations regarding Areas of Uncertainty

Areas of Uncertainty	Significant Quotations
Technological Uncertainty	Besides the employees I don't think other stakeholders have had a big influence on our technology platform. (Interview 9)
	Our engineers and our scientists are constantly working with their community. (Interview 8)
	We engage with different associations, whether it's farm groups or biotechnology associations that can play important roles here. (Interview 7)
	Our engineers don't have all the answers, so they call the equipment suppliers and they have a conversation with their technical experts, explain the problem and get feedback on how to solve it. Or maybe our scientific team has problems with engineering a pathway, so they're creating a consulting agreement for example with a research institute or university to basically pay for access to the experience that we may not have had internally. (Interview 6)
	I think that's more us than anybody else. (Interview 5)
	We have a very good scientific advisory board which meets every quarter. (Interview 4)
	Not really. I mean our situation is very different. I mean we're the first company in the world to produce such products. (Interview 3)
	We have a pretty good industry network within the biotech community where we can tap into. We also have a really great set of advisors that can provide feedback along the way from R&D perspective. (Interview 2)
	Besides our employees I would say none, except perhaps academic researchers. (Interview 1)
Commercial Uncertainty	Before launching the crowdfunding campaign we had done a lot of testing with a lot of people within the biotech and our target industry. So we had already early feedback. (Interview 9)
	We engage with different farm associations and retailers to look at the economic viability of technology and to determine whether or not there is a market for the product or which product to bring to market. (Interview 7)

	That's usually done in collaboration with the customer. Everything we've introduced is intended to be a replacement for an existing incumbent. So they already have a good idea of what the price of the product they're buying is and what price they would like to buy that. (Interview 5)
	One member of our advisory board is the biggest sort of agent provocateur in terms of understanding where this can go and what the economic opportunity would be and whether it's feasible. So he helps us a lot in that regard. In general I think economics-wise we have got a good internal team and then the advisory board bringing that extra area. (Interview 4)
	No, not really. I mean it is a shame in many ways that when you bring forward something that's so innovative the majority of the stakeholders out there are actually telling you all the reasons as to why you will fail. (Interview 3)
	Our investors have been very, very helpful with understanding, which consumer bases are most interested and they connected us with bigger companies which are looking for alternative sources of ingredients. From a cost reduction point of view our advisory network was very helpful. (Interview 2)
	Yes, absolutely. I would say that's when we reach out to all of the stakeholders to find out what they like about it, what they don't like, what exists in the market or exists currently in the supply chain that they feel needs to be changed. And that is very useful information. (Interview 1)
Social Uncertainty	Regarding social and environmental impacts we get the best feedback and the most useful and important feedback absolutely from the non-profit community, from social and environmental activists. Also policy makers have been good, in terms of giving us insight to what is it that they're looking for. And then finally I would say costumers, because they're so close to their own consumers they're often asking questions as well. (Interview 8)
	I mean it depends on the technology, but it could be farmers, retailers or end consumers as well. So they each look at the technology from a different perspective and are asking different questions about the sustainability and the economics of the products. Also local communities play a role when you're looking to disseminate your technology, when you're applying it in the fields; they're going to be interested or concerned with the local impact. (Interview 7)
	Because of where we sit in the value chain - we are not the ones building plants or the ones responsible for an asset in a particular location that will have a social and environmental impact - we tend to be one step removed from those conversations. (Interview 6)
	Probably governmental organizations are most concerned about this. For example when we take a modified organism into Brazil we have to assemble a dossier that describes the environmental impact of the release of this organism. So we did a lot of testing on soil degradation and persistence in the environment, fish feeding studies, worm feeding studies, mammal feeding studies, degradation of the final product, how long they persist, impacts on water quality and so on. And if anything we set a very high bar, because we did a lot of testing that was sort of above and beyond what they were originally asking for, simply because we wanted to know: What's the potential impact and is there any real environmental hazard? (Interview 5)
	An association we interact with, which kind of acts as a liaison between technology developing companies and universities also is a sounding board for what the public is interested in and so we draw often some of their resources and some of the insight they provide. (Interview 4)

	This was done in cooperation with different research institutes, local research and control units and the local communities for each of our programs. (Interview 3)
	We've engaged some vegan organizations, animal welfare protection groups, wildlife organizations to kind of let them know what we're doing. And it has been incredibly well received from that perspective of trying to provide consumers with an alternative choice through our product. Furthermore we are engaging an organization that does life cycle analyses to really quantify: How much water are we really saving, how much energy, how much land and how much greenhouse gas emissions are we preventing? (Interview 2)
	Probably our NGO stakeholder and our quasi-government, quasi-academic stakeholders. Engaging with some non-profits have definitely made us think about: How can we be better at sourcing? How can we make it both economical, but also ethical? And I think from that perspective it's a very important point to consider. (Interview 1)
Organizational Uncertainty	I think the community engagement that we've done in Brazil and engaging with influencers and people that help to say 'your product is fantastic', helps to amplify that's where the benefit of all that hard work we're doing is realized, because it gives us the credibility and integrity. (Interview 8)
	I mean the media has a role in helping us to be able to communicate the benefits as well as different associations that are relevant, whether it's farmers, biotechnology associations or others, but can help disseminate the information. (Interview 7)
	It's going to be our licenses' customers and the brand owners. Because they ultimately need to have a reason for wanting to invest and making a change to what we offer. (Interview 6)

5 THE INFLUENCE OF STAKEHOLDER ENGAGEMENT ON UNCERTAINTY – A STRUCTURE EQUATION MODEL APPROACH

In the previous chapter it was demonstrated that uncertainty is a key feature of management research and, in particular, for innovation and entrepreneurship research (Sarasvathy et al. 2005; Knight 1921; York and Venkataraman 2010; Shane and Eckhardt 2005; McKelvie et al. 2011). However, there no quantitative research was conducted on the role of stakeholders in reducing such uncertainty. Building on the insights of the qualitative study in the previous chapter, in this chapter the relation of stakeholder engagement and uncertainty is scrutinized further. Moreover, hypotheses are developed and tested using structure equation modelling. This study was built on the previous one, using the same theoretical basis:

a) The supercategories of stakeholders:
    - Direct stakeholders
    - Indirect stakeholders
b) The four categories of uncertainty defined by Hall et al. (2014) and Hall and Martin (2005):
    - Technological uncertainty (tU)
    - Commercial uncertainty (cU)
    - Social uncertainty (sU)
    - Organizational uncertainty (oU)

However, to ensure a rigorous approach, the literature review on the four different categories of uncertainty was extended. It was based on the systematic literature review on uncertainty of innovation by Jalonen (2012). This review follows in the next section. This is followed by an extension of the model to include the concept of knowledge transfer, which is vital for explaining the influence of stakeholder engagement on uncertainty.

5.1 Uncertainties of Innovation Processes

5.1.1 Technological Uncertainty

The technological aspects of innovations are full of uncertainties and ambiguities (Narvekar and Jain 2006; Olson et al. 2014), often due to the novelty of the technology (Swink 2000; Tatikonda and Montoya-Weiss 2001; Tidd and Bodley 2002; Nieto 2004; Carbonell and Rodriguez 2006). According to Rogers (2003), technology is widely understood to include the technical tools and the knowledge required to use the tools. In line with this twofold perspective, Harris and Woolley (2009) divide technological uncertainty into uncertainty regarding product specification (i.e. technical tools) and production processes (i.e. knowledge). With respect to product specification, Jalonen (2012) emphasizes that uncertainty comes from (at least) four distinct aspects: technical feasibility, usefulness, functionality and quality (Allen 1982; Leifer et al. 2001; Hall and Martin 2005; Buddelmeyer et al. 2010; Hall et al. 2011). Regarding production processes Jalonen identifies (at least) two uncertainty components, namely the skills and knowledge required to use the new technology (Veryzer 1998; Nieto 2004; Ortt and Smits 2006; Carbonell and Rodriguez 2006; Cantarello et al. 2011).

5.1.2 Commercial Uncertainty

With respect to commercial uncertainty, Jalonen (2012) identifies three components in his literature review. These concern customers, competitors and price development. Because the main sources of uncertainty are caused by customers, one can identify uncertain demand, unknown behavior and unclear customers' needs (Souder and Moenaert 1992; Leifer et al. 2001; Tatikonda and Montoya-Weiss 2001; Gilbert and Cvsa 2003; Freel 2005; Hall and Martin 2005; Rose-Anderssen et al. 2005; Carbonell and Rodriguez 2006; Naranjo-Gil 2009; Corrocher and Zirulia 2010; Cantarello et al. 2011). In addition, a lack of knowledge about the behavior of competitors is a second component of commercial uncertainty; organizations cannot predict competitors' intentions with any certainty (Souder and Moenaert 1992; McDermott 2002; Naranjo-Gil 2009; Banerjee and Chatterjee 2010). Burgers et al. (1993) call these two uncertainties demand and competitive uncertainty. They describe demand uncertainty as the uncertainty that arises from changes in purchasing patterns, for which predictability is low in dynamic industries (e.g., highly innovative industries). In contrast, competitive uncertainty is described as the uncertainty that arises from competitive interdependence (competitive actions have direct effects on market positions).

As a third component of commercial uncertainty, Jalonen emphasizes uncertain price developments associated with competing products and services. He refers to Gibbons and Littler (1979), who found that difficulty in forecasting the price developments of key materials needed for providing new products might cause uncertainty in innovation processes.

5.1.3 Social Uncertainty

What Hall et al. (2014) describe as social uncertainty (societal impact on or by society, legitimization and acceptance of the technology) is divided into consequence uncertainty, social/political uncertainty and acceptance/legitimization uncertainty in Jalonen's literature review.

The consequences of innovation are mostly uncertain because they cannot be predicted in advance. Apart from the impact related to the usefulness of an innovation, other impacts on society are unpredictable (Lambooy 2006). Such uncertainty exists because often the relations between inputs and possible outputs cannot be determined (Roffe 1998; Foster 2010). The assessment of long-term consequences of innovation is especially connected with high uncertainty (Gerwin and Tarondeau 1982; Robertson and Gatignon 1986; Cooper 1998; Collingridge 1982). However, it is not only the innovation activities of organizations that impact society; societal activities also impact innovating organizations. Such uncertainty arises from interactions between the innovating organization and external partners or stakeholders, and depends on the quality, complexity and dynamics of the relations (Cantarello et al. 2011; Bonifati 2010; Ortt and Smits 2006; Arias 1995; Sartorius 2006). These relationships influence organizational decision making and might cause an adaption of strategy due to external pressure (Hall and Martin 2005; Hall et al. 2014).

With respect to the legitimization and acceptance of innovation, one can differentiate between two components that cause uncertainty (Jalonen 2012): cognitive legitimacy and socio-political legitimacy (Aldrich and Fiol 1994; Hall et al. 2011). The first refers, *inter alia*, to the knowledge potential users need to

have to use an innovation. Shepherd and Zacharakis (2003), for example, conclude that "priority should be given to building customer knowledge of the product" (Shepherd and Zacharakis 2003, p. 148) to increase the cognitive legitimacy of an organization. The latter refers to individuals' values and their fit with the new technology. Several researchers argue that innovation that does not fit the values and/or norms of individuals or collectives causes uncertainty with regard to its acceptance (Rappert and Brown 2000; Geijsel et al. 2016; Mallett 2007; Degeling 2009; Lehoux et al. 2009; Schlich 2007). Overall, the acceptance of an innovation depends on the knowledge base of potential users and the fit with their existing world view and current thinking (Hurst 1982).

5.1.4 Organizational Uncertainty

According to Hall, organizational uncertainty is concerned with the ability of an organization to appropriate the benefits of a new technology. Even if such a new technology (product, process, service) is technologically and commercially viable, the innovator will not be able to capture its benefits if there is no appropriability regime in place, which includes protection mechanisms for intellectual property and the possession of complementary assets (Hall et al. 2014; Teece 1986). In general, organizational uncertainty arises from a lack of knowledge regarding the effectiveness of management activities that are intended by organizations to support innovation behavior, and to capture and protect the competitive advantages of innovation (Jalonen 2012; Cohen and Levinthal 1990). This might include uncertainties associated with changing members of project teams, the required resources and competencies, managing relationships within the organization and collaboration with partners (Souder

and Moenaert 1992; Osborne 1996; Leifer et al. 2001; Muller et al. 2005; Freel 2005; Hall and Martin 2005; Mitleton-Kelly 2012).

5.2 Knowledge Transfer

Stakeholder theory, as well as the theory of uncertainty, suggest that uncertainty can be reduced through the transfer of information from stakeholders to the innovating organization. To reduce uncertainty, the innovating organization needs to be able absorb such transferred knowledge. This knowledge receipt has been analyzed in terms of the absorptive capacity of the recipient (Grant 1996; Cohen and Levinthal 1990; Zahra and George 2002; Lane and Lubatkin 1998; Albort-Morant et al. 2018). The concept of absorptive capacity originates from the seminal work of Cohen and Levinthal (1990), who define it as an organization's ability to value, assimilate and apply new knowledge. The theory of absorptive capacity was reconceptualized by Zahra and George (2002), who distinguish between two dimensions: potential and realized absorptive capacity. These dimensions consist of four subsets that comprise an organizations absorptive capacity: acquisition (identification and acquisition of valuable external knowledge); assimilation (effective assessment, processing and understanding of newly-acquired external knowledge); transformation (capability to combine acquired knowledge and existing related knowledge); and exploitation (incorporating the acquired knowledge into operations). This shows that absorptive capacity is a key competence for innovating organizations to reduce uncertainty. They need to be able incorporate external knowledge and use it to their benefit. Hence, absorptive capacity plays a crucial role in this study and it can even be argued that stakeholder engagement can only reduce uncertainty indirectly through

the increase of absorptive capacity. This is because the reduction of uncertainty is highly dependent on the transfer of information and knowledge (conceptualized through absorptive capacity). This line of argumentation is also supported by the preceding study, in which it was shown that the main benefit of stakeholder engagement for entrepreneurial organizations active in advanced biotechnology is the exchange of information.

5.3 Hypotheses

Based on the above literature review and the preceding explorative study, the hypothesis that stakeholder engagement has an indirect, negative influence on the uncertainty of firms through an increase of absorptive capacity was formulated. Moreover, this is especially true for those active in the field of disruptive technology development (biotechnology firms), which are the focus of this study. To further examine these relationships between stakeholder engagement, absorptive capacity and uncertainty, especially with regard to the categories of stakeholders (engagement of direct [dSE] and indirect stakeholders [iSE]) and uncertainty (technological, commercial, organizational, social), the following hypotheses were developed to be tested by a structural equation model (SEM) approach:

H1: The influence of stakeholder engagement (SE) on uncertainty (U) is indirect/fully mediated by absorptive capacity (AC).

H2: iSE and dSE increase AC.

H3: AC reduces all four types of U.

H4: iSE and dSE indirectly reduce all four types of U.

In accordance with the preceding study, in this study the following hypotheses were additionally tested to compare the levels of uncertainty reduction due to the engagement of direct and indirect stakeholders:

H5: sU is reduced mainly by iSE.

H6: tU is reduced mainly by dSE.

H7: cU is reduced mainly by dSE.

5.4 Research Design

The Structure Equation Model (SEM) is a statistical method for modeling causal networks of effects simultaneously instead of in a piecemeal manner. It offers extensive, scalable and flexible causal-modeling capabilities. A prime advantage of SEM is the ability to include unobserved variables in causal models, which enables researchers to model abstract constructs comprised of many indicators, each of which is a reflection or a dimension of the unobserved construct. The overall strength of SEM is that it can test the plausibility of an entire collection of propositions simultaneously and model multiple independent and dependent variables, chains of causal effects and indirect effects, and the unobserved constructs that variables are meant to measure (Westland 2015). These methodological features made SEM a perfect fit for the purpose of this study. The updated guidelines by Hair et al. (2017a) were used to choose the best SEM approach, that is, to select either covariance-based (CB-SEM) or variance-based partial least squares (PLS-SEM), PLS-SEM was chosen, for three main reasons: compared to CB-SEM, PLS-SEM is the better choice for (1) exploratory research; (2) models including formative constructs;

and (3) relatively small sample sizes (Hair et al. 2017b; Lowry and Gaskin 2014; Rigdon 2016; Hair et al. 2017a).

The following models were established to test the hypotheses. In both models the expected results, predicted by the hypotheses above, are indicated along the paths. In these models, the indicators of absorptive capacity are modeled as reflective because the various items are interchangeable. Any changes in absorptive capacity should be matched by analogous changes in all of its indicators. Contrariwise, the indicators of stakeholder engagement and uncertainty are characterized as formative, because the constructs are composites of indicators rather than a cause of them. Removing or replacing any of the constructs' items would change their meaning. Since these indicators are not interchangeable, they are framed as formative rather than reflective.

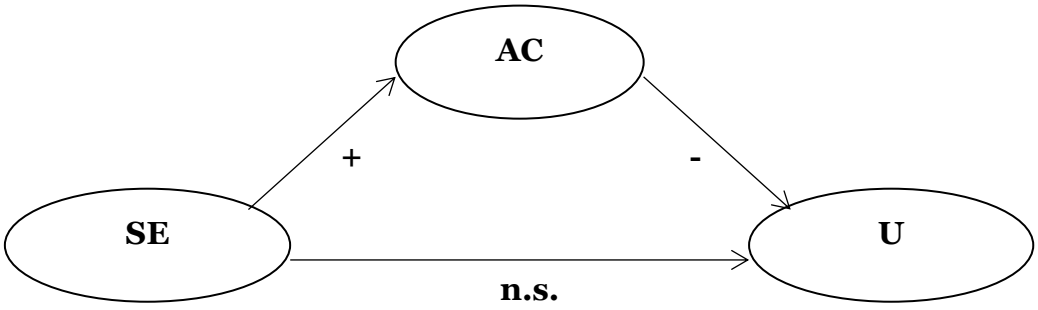


Figure 6: H1 Model

Hence, the model for testing H1 (H1 model – Figure 6) comprised the reflective factor absorptive capacity and two formative factors, namely stakeholder engagement and uncertainty. Absorptive capacity was measured as described in Annex III. For stakeholder engagement and uncertainty, all the items for stakeholder engagement (dSE and iSE) and uncertainty (oU, cU, tU, and sU)

were used as indicators. All the items represented important theoretical dimensions of uncertainty.

The model for testing H2-H7 (H2-H7 model -Figure 7) consisted of the reflective factor absorptive capacity and the formative factors engagement of direct stakeholders, engagement of indirect stakeholders, technological uncertainty, commercial uncertainty, social uncertainty and organizational uncertainty, which were measured as described below and in Annex III.

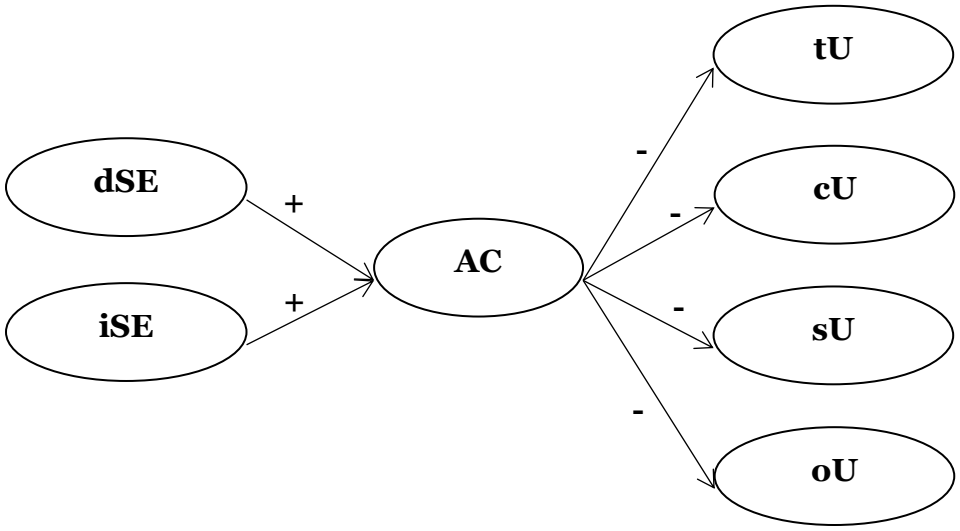


Figure 7: H2-H7 Model

5.4.1 Measures

Due to the novelty and explorative character of this research design, a heuristic approach was used to construct the various factors. The factors used in the proposed model, including the way they were measured, are described in Annex III. The measure factors 1 and 2 were developed according to the stakeholder theory literature and factors 3-6 according to Hall et al.'s

descriptions of the uncertainty categories (Hall et al. 2014), as well the further literature in the area of uncertainty of innovation described above.

5.4.1.1 Stakeholder Engagement

There are established metrics for measuring stakeholder engagement activities (e.g. Ayuso et al. 2011), but the focus of these are often on the general level of engagement activities, with no differentiation between various groups in detail. If so, the focus, for example, is on internal (employees) and external stakeholder (e.g. SAM Research Corporate Sustainability Assessment Questionnaire). As such, the metrics did not fit the purpose of this study. Thus, a new measurement model for stakeholder engagement was developed.

As described above, stakeholder categories are divided into two supercategories: direct and indirect stakeholders. For the purpose of this study, this twofold perspective was utilized for the measurement of stakeholder engagement. Direct as well as indirect stakeholder engagement were constructed as formative factors, because both consist of the distinct interaction intensity with the stakeholder categories and hence represent components of the constructs. The engagement activities were measured by items asking for the intensity with which the organization engages with the single stakeholder groups belonging to the specific supercategory (employees, customers, investors, shareholders, financial institutions, business partners, suppliers, advisors, local communities, governmental organizations, regulators, competitors, media, NGOs, activists, universities and research institutes). The instruction for the participants were as follows:

“Stakeholders often play a vital role for companies, but there are variations in the intensity of engagement. Some stakeholders are more important than others. If you think of your organization, how would you rate the intensity of stakeholder engagement?”

To measure the intensity of interaction between the organization and its stakeholders, the metric developed by Frey et al. (2006), with minor adjustments of wording for better context fit, was used. They used a six-scale metric to measure interactions between partners. The scale points used in this study were as follows:

0. No interaction at all
1. Networking: Aware of organization; loosely defined roles; little communication; decisions are made independently
2. Cooperation: Provide information to each other; somewhat defined roles; formal communication; decisions are made independently
3. Coordination: Share information and resources; defined roles; frequent communication; some shared decision making
4. Coalition: Share ideas and resources; frequent and prioritized communication; have a vote in decision making
5. Collaboration: Belong to one system; frequent communication is characterized by mutual trust; consensus is reached on all decisions

5.4.1.2 Uncertainty

The descriptions of the different categories of uncertainty given above were used as a springboard to derive the measures and items for the four uncertainty constructs. In addition, literature in which the measurement of the constructs

or similar constructs was dealt with was consulted. In general, it can be said that all four uncertainty factors were constructed as formative constructs, because they were combinations of distinct components, as the different descriptions above indicate. A table with all the factors and items, which were measured on a seven-point Likert scale, can be found in annex III. The following instruction was given:

"Below you can find several statements regarding important technological, commercial, societal and organizational aspects of innovation processes in biotech companies. To what extent do you agree/disagree with these statements in the context of your organization? (1 = strongly disagree, 7 = strongly agree)"

5.4.1.2.1 Technological Uncertainty

Scales to measure (perceived) technological uncertainty had previously been established (Song and Montoya-Weiss 2001; Atuahene-Gima 2004; Heavey and Simsek 2013). However, they measured technological uncertainty in relation to whole industries. Because the focus of this study was uncertainty with regard to single organizations, a new measure was developed for technological uncertainty. The six distinct components of technological uncertainty mentioned in the literature review above (feasibility, usefulness, functionality, quality, skills, and knowledge) were used as a basis. Nevertheless, the items from the previous studies that dealt with technological uncertainty were used as a heuristic springboard (e.g., one item was adopted from Song and Montoya-Weiss [2001] with minor changes). The following items were used to measure technological uncertainty:

- Feasibility (TU_FEASI): At an early stage of the development cycle we already know if the technology/product development will be technologically feasible (reverse coded).
- Usefulness (TU_USE): It is very difficult to predict how useful our technology/product will be for us in the future.
- Functionality (TU_FUNCT): Already at an early stage of the development cycle we can describe the function of new technologies/products that we develop in detail (reverse coded).
- Quality (TU_QUALITY): Already at an early stage of the development cycle we can make precise statements about the quality of new technologies/products (reverse coded).
- Skills (TU_SKILLS): We often use external skills/competences for the development of our technology/products.
- Knowledge (TU_KNOW): Our technology is a ""well-developed science,"" i.e., there is a well-developed body of scientific know-how, there are many well-known cause and effect relationships and the predictive state-of-the-art is very high (reverse coded).

5.4.1.2.2 Commercial Uncertainty

The literature on commercial uncertainty mentioned above indicated that commercial uncertainty had three distinct components: uncertainty regarding (1) the demand by customers; (2) competition and (3) price developments. These could be used to formatively construct this factor Hence, commercial uncertainty was measured on three items: the dynamism of customer demands, competition and price development. For the development of the single items, the measurement model for market uncertainty by Sainio et al. (2012) was used as a starting point. The items for demand and competition uncertainty were directly adopted from Sainio et al. 2012 and complemented with a third item for price uncertainty. Hence the following items were used to measure commercial uncertainty:

- Demand (CU_DEMAND): In our sector it is difficult to forecast changes in the needs and demands of customers.
- Competition (CU_COMP): It is impossible to forecast market competition.
- Price (CU_PRICE): It is difficult to forecast price developments of needed materials/resources in our sector.

5.4.1.2.3 Social Uncertainty

As described above, social uncertainty consists mainly of four aspects: (1) unknown impacts on society; (2) external pressure; (3) ease of use of technology for potential users; and (4) the acceptance of the new technology. These four components were used to measure social uncertainty. To measure impact uncertainty, the respondents are asked to what extent they systematically explored the impacts of their technology on society and whether they were aware of such impacts (single-item). In a similar vein, the respondents were asked to what extent they needed to adapt strategy due to external pressure. Metrics already existed for measuring the ease of use of technology. However, in such studies, for example, 12-item instruments (e.g. Szajna 1996) were used because ease of use was a primary research object. For this study, ease of use was measured as a single item by asking about the intensity of training users or customers needed to use the technology or products (cognitive legitimacy). To measure the fourth aspect of social uncertainty—the acceptance of the new technology—as a single-item, the respondents are asked to assess the acceptance rate within society (socio-political legitimacy). Thus, social uncertainty was measured using the following items:

- Impacts on society (SU_IMPACTS): We systematically assess impacts of our technology/product on society and are very much aware of such impacts (reverse coded).
- External pressure (SU_EXTERN): We adapt our strategy regularly to compensate external pressure.
- Ease of use of technology (SU_EOU): Users/Customers need intense training to be able to use our technology/product.
- Acceptance of the new technology (SU_ACCEPT): Our technology/products have a very high acceptance rate within society (not only with end users) (reverse coded).

5.4.1.2.4 Organizational Uncertainty

The literature on organizational uncertainty above shows that it arises from a lack of knowledge regarding the effectiveness of management activities that are used by organizations to support innovation and to capture and protect the competitive advantages of new processes, products or services. The implementation of such activities is also described as an appropriability regime that includes mechanisms to protect intellectual property and complementary assets (Hall et al. 2014; Teece 1986). Levin et al. (1987) identified six key mechanisms of appropriation used by firms to capture and protect the competitive advantages of new or improved processes and products. Hence, these mechanisms of appropriation (patents to prevent duplication and secure royalty income, secrecy, lead time, moving quickly down the learning curve, and complementary sales and service efforts) for developing the items for measuring organizational uncertainty were adopted, leading to the following items:

- Patents to prevent duplication (OU_IP): We follow a strong IP (intellectual property) protection policy in filing patents to prevent

duplication and secure royalty income (reverse coded).

- Secrecy (OU_SECRET): All employees are legally bound to follow our secrecy policy (reverse coded).
- Lead time (OU_TIME): Compared to competitors we have a short lead time which allows us a short time to market (reverse coded).
- Moving quickly down the learning curve (OU_CURVE): We move quickly down the learning curve compared to competitors (reverse coded).
- Complementary sales and service efforts (OU_SERVICE): Compared to competitors we offer extraordinary sales and service quality (reverse coded).

5.4.1.3 Absorptive Capacity

Various approaches to measuring absorptive capacity were found in the literature. Some researchers used R&D spending as a percentage of firm sales (Stock et al. 2001; Tsai 2001; Lane and Lubatkin 1998), whereas others developed detailed scales and constructs to measure absorptive capacity, differentiating between potential absorptive capacity and realized absorptive capacity with various factors (Camisón and Forés 2010; Flatten et al. 2011; Albort-Morant et al. 2018; Jansen et al. 2005). This differentiation between potential absorptive capacity and realized absorptive capacity was not relevant for his study. Thus, the approach of Szulanski (1996), who measured absorptive capacity as a single construct, was used. The nine-item scale from Szulanski was also used by Jansen et al. (2005) to further assess the construct validity of their measures for potential and realized absorptive capacity by comparing the scores of their study variables with the separate overall measure of absorptive capacity. They concluded that the correlations between the study variables and the overall measure of absorptive capacity were positive and significant,

suggesting evidence for the convergent validity of their construct. This also implies the validity of the overall measurement of absorptive capacity, according to Szulanski (1996). Hence, the items to measure absorptive capacity used in this study were adopted from Szulanski and adapted to the purpose of this study by using Jansen et al. (2005). All the items are measured on a seven-point scale, in which 1 was "strongly disagree" and 7 was "strongly agree." Seven point-scales are widely used in literature in this context (e.g. Jansen et al. 2005; Albort-Morant et al. 2018; Flatten et al. 2011). The instruction given to participants was:

"Below you can find several statements related to the role of knowledge within organizations. If you think of your organization, to what extent do you agree or disagree? (1 = strongly disagree, 7 = strongly agree)"

The following items were used to measure absorptive capacity:

- Common language (AC_LANG): Our employees have a common language regarding our technology/products.
- Vision (AC_VISION): We have a clear vision of what we are trying to achieve through the acquisition of external knowledge.
- State-of-the-art information (AC_STATE): We have information on the state-of-the-art of available external knowledge.
- Division of roles (AC_ROLES): Our organization has a clear division of roles and responsibilities.
- Skills (AC_SKILLS): We have all necessary skills to gain and use external knowledge (e.g. networking, high market awareness, usefulness and demand of/for information).
- Technical competence (AC_TECH): We have the technical competence to absorb new knowledge (e.g. knowledge management tools, recording and storing of knowledge, knowledge sharing platforms).
- Managerial competence (AC_MANAGE): We have the managerial

competence to absorb new knowledge (e.g. regular internal and external meetings, high information exchange, clear process structures).

- Exploitation (AC_EXPLOIT): It is well known who can best exploit new information within our organization.
- Problem solver (AC_SOLVE): It is well known who can help solve problems within our organization.

5.4.2 Sample and Data Collection

The Biotechgate database was used for the survey. Biotechgate is a global leading database for the biotech, pharma and medtech industries. It contains over 49,000 (by February 2018) company profiles, with information on available licensing products, financing rounds, key management, technology platforms and more. It is owned and published by the Swiss-based Venture Valuation AG. An outstanding feature of Biotechgate is that it cooperates with more than 30 industry associations and development agencies, such as Bio Deutschland, BIOTECanada, Swiss Biotech Association, CLSA and Bio Taiwan, which made the database an extremely good fit for this study.

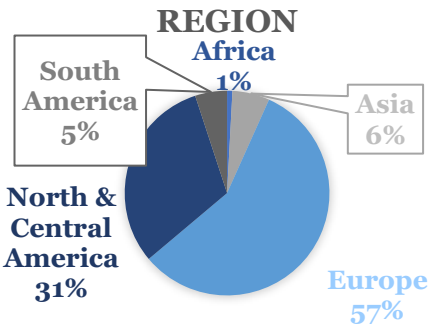
The scope was further narrowed by using the sector "Biotechnology – other" in the database. This category included the following subsectors: AgBio, Cosmetics, Environmental, Food, Industrial Biotechnology, Nutraceuticals, Veterinary and Other. This left about 4.000 firms (by February 2018) within the scope of this study. This focus was chosen because these subsectors included all the dedicated biotech companies in the database, except those active in the field of therapeutics and diagnostics (which is highly regulated) and RnD services (which do not have own biotech products). Also, one might argue that these subsectors are characterized by high uncertainty. Most firms active in these subsectors explore new fields and thus cannot build upon

previous experiences or use other firms as role models. Due to their high level of innovativeness and uncertainty (Schoonmaker et al. 2017), these biotechnology subsectors, were considered an extremely good fit for this study.

Before the survey was conducted, a pre-test of the questionnaire was performed. Nineteen researchers from the research methods group at the Institute for Technology Assessment and Systems Analysis at the Karlsruhe Institute of Technology and the Schumpeter School of Business and Economics at the University of Wuppertal tested the questionnaire and provided valuable feedback regarding comprehensibility and functionality with a view to optimizing the survey process. This led to minor changes in the questionnaire. The survey was anonymous by design and hosted on the renowned SoSci Survey platform, with servers based in Germany.

The database included 4,069 datasets within the selected sectors. These were reviewed if (a) specific contact persons and (b) e-mail addresses were included. Datasets without contact persons (376) or e-mail addresses (508) were excluded. In addition, duplets (35) were removed, which left the maximum potential sample size at 3,150. All 3,150 contacts were included in the mailing list for sending out the invitation for participating in the survey. Sixty e-mail addresses were invalid. Hence, a total number of 3,090 contacts had the opportunity to participate in the survey. The survey started on 7 March 2018 and was open for four weeks. During that time, two reminders were send out, the first on 12 March 2018 and the second on 20 March 2018. The survey was closed on 5 April 2018 because it was unlikely that further reminders would yield additional datasets. A total of 119 questionnaires were completed and 46 were started but not completed. This resulted in a response rate of 5.34% (165/3090) and a completion rate of 3.85 % (119/3090). The following figures

comprise an overview of the characteristics of the 119 participants of the survey.



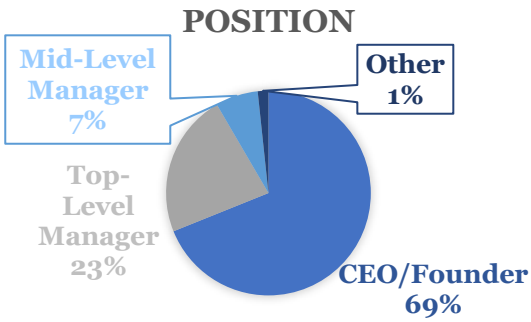


Figure 8: Participants by Region

Figure 9: Participants by Position

It was evident that the majority of the participants were based in Europe (57%) and North and Central America (31%). An indicator that indicates an extremely high quality of data is that more than 69% of the participants were CEOs/Founders and 23% were top-level managers, which is of high relevance for this study because it examines general management aspects.

The biotech subsectors in which the organizations of the participants are primarily active are shown in the following figure.

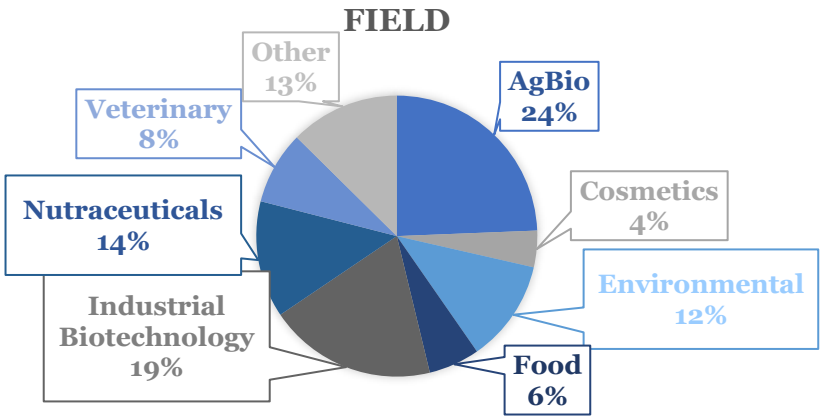


Figure 10: Participants by Field

The three biggest subsectors represented were Agricultural Biotechnology (AgBio) (24%), Industrial Biotechnology (19%) and Nutraceuticals (14%).

Whereas the sectors represented in the sample of participants were highly heterogeneous, the size of the organizations represented was highly homogenous; 90% of the organizations fell under the European Commission's definition of SMEs[5].

5.4.3 Data Analysis

As mentioned above, the research models and hypotheses were tested by Partial Least Squares (PLS), a variance-based structural equation modeling (Hair et al. 2017b). The primary justifications for the use of PLS were: (1) the explorative character of the study; (2) the modelling of reflective and formative

[5] Staff headcount < 250 **AND** (Turnover ≤ € 50 m **OR** balance sheet total ≤ € 43 m).

factors; and (3) the sample size (Hair et al. 2017b; Lowry and Gaskin 2014; Rigdon 2016; Hair et al. 2017a). The SmartPLS 3 software was used in this study.

5.4.3.1 Results

The analysis for both models was done according to Hair et al.'s (2017c) description. Several tests were performed to ensure the validity and reliability of the outer model, which led to minor adaptions of the models. Because this study has an explorative character and due to the sample size, a liberal approach with a p-value threshold of 0.1 for paths being significant was applied.

5.4.3.1.1 Model for testing H1

The reflective construct absorptive capacity (AC) was evaluated first. The PLS (default, factor) and bootstrapping (5000 subsamples, factor) was calculated to assess its reliability and validity. After the first round of assessment, according to the procedure described by Hair et al. (2017c), the assessment of the composite reliability, indicator reliability, AVE and Fornell-Larcker criteria the indicator AC_LANG was excluded (loading below 0.7 and improvement of composite reliability after exclusion[6]). After the exclusion composite reliability (0.898)[7], convergence validity (no other indicator qualified for exclusion &

[6] Exclusion criteria for reflective factors (Hair et al. 2017c): Loading between 0.4 and 0.7 and improvement of composite reliability after exclusion; or loading below 0.4.

[7] Composite reliability between 0.7 and 0.95 (Hair et al. 2017c; Hair et al. 2017b; Henseler et al. 2012; Garson 2016).

AVE = 0.527[8]) and discriminant validity (Fornell-Larcker criteria satisfied[9]) were established. The outer loadings of the absorptive capacity indicators and their significance can be found in the following table.

Table 6: Reflective Factor Loadings H1 Model

Indicator	Loading	P-value
AC_EXPLOIT <- AC	0,857	0,000
AC_MANAGE <- AC	0,797	0,000
AC_ROLES <- AC	0,639	0,000
AC_SKILLS <- AC	0,664	0,000
AC_SOLVE <- AC	0,773	0,000
AC_STATE <- AC	0,629	0,000
AC_TECH <- AC	0,804	0,000
AC_VISION <- AC	0,597	0,000

Regarding the formative factors stakeholder engagement (SE) and uncertainty (U), it is argued that factor validity is established due to the content validity underlying the construct measurement. An exclusion would have changed the character of stakeholder engagement and uncertainty essentially, because they are indicators of theoretically important dimensions (Hair et al. 2017b). Also, the analysis of the VIFs (all below 5) showed no collinearity issues in the outer formative model (Hair et al. 2017b). After the assessment of the outer model

[8] AVE lager than 0.5 (Garson 2016; Chin 1998).

[9] AVE greater than the squared latent variable correlations (Fornell and Larcker 1981; Garson 2016).

and the adaptions mentioned above, the reliability and validity of the outer model were established.

In order to assess the predictive power of the model, PLS (default, path) and bootstrapping (5000 subsamples, path) were calculated, with a special interest in collinearity, path coefficients, significance levels and R^2. Collinearity was not an issue in the model, because all the VIFs were below 5. The results of the path coefficients and R^2 values are shown in Figure 11.

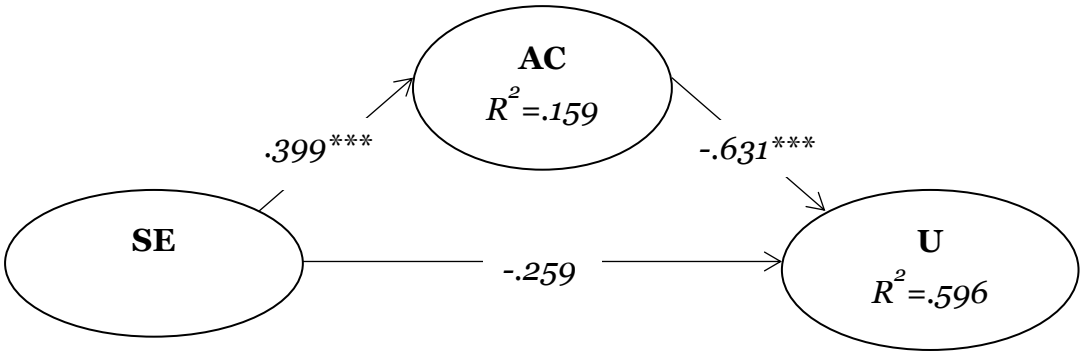


Figure 11: Results H1 Model

* Indicates significant path: *p<0.1, **p<0.05, ***p<0.001

Furthermore, the indirect path SE->AC->U was significant, with a path coefficient of -.252 and p<0.05 (not illustrated in the figure above). This shows that the effect of stakeholder engagement on uncertainty is indirect/fully mediated (Hair et al. 2017b; Zhao et al. 2010).

5.4.3.1.2 Model for testing H2-H7

The analysis described for model H1 above was also performed for the model for testing H2-H7. The evaluation of reliability and validity of the reflective construct absorptive capacity resulted in the exclusion of AC_LANG. Composite reliability (0.898), convergence validity (no other indicator qualified for exclusion & AVE = 0.527) and discriminant validity (Fornell-Larcker criteria satisfied) were established after exclusion. Cronbachs Alpha was 0.868. The outer loadings of the absorptive capacity indicators and their significance can be found in Table 7.

Table 7: Reflective Factor Loadings H2-H7 Model

Indicator	**Loading**	**P-value**
AC_EXPLOIT <- AC	0,859	0,000
AC_MANAGE <- AC	0,798	0,000
AC_ROLES <- AC	0,648	0,000
AC_SKILLS <- AC	0,666	0,000
AC_SOLVE <- AC	0,775	0,000
AC_STATE <- AC	0,624	0,000
AC_TECH <- AC	0,802	0,000
AC_VISION <- AC	0,591	0,000

For this model the same line of argumentation was followed regarding the validity of the formative factors stakeholder engagement of direct (dSE) and indirect stakeholder (iSE), technological (tU), organizational (oU), commercial (cU) and social uncertainty (sU).

The aspect of content validity was dealt with and established in earlier sections of this chapter. No indicator was excluded, because an exclusion would have essentially changed the character of the constructs for the engagement of direct stakeholders, engagement of indirect stakeholders, technological uncertainty, organizational uncertainty, commercial uncertainty and social uncertainty, because they were the only indicators of the theoretically important dimensions of the factors (Hair et al. 2017b). The VIFs were analyzed for collinearity and were all below 5 (Hair et al. 2017b), showing no collinearity issues in the outer formative model. Following the assessment of the outer model and the adaptions of absorptive capacity, reliability and validity were established.

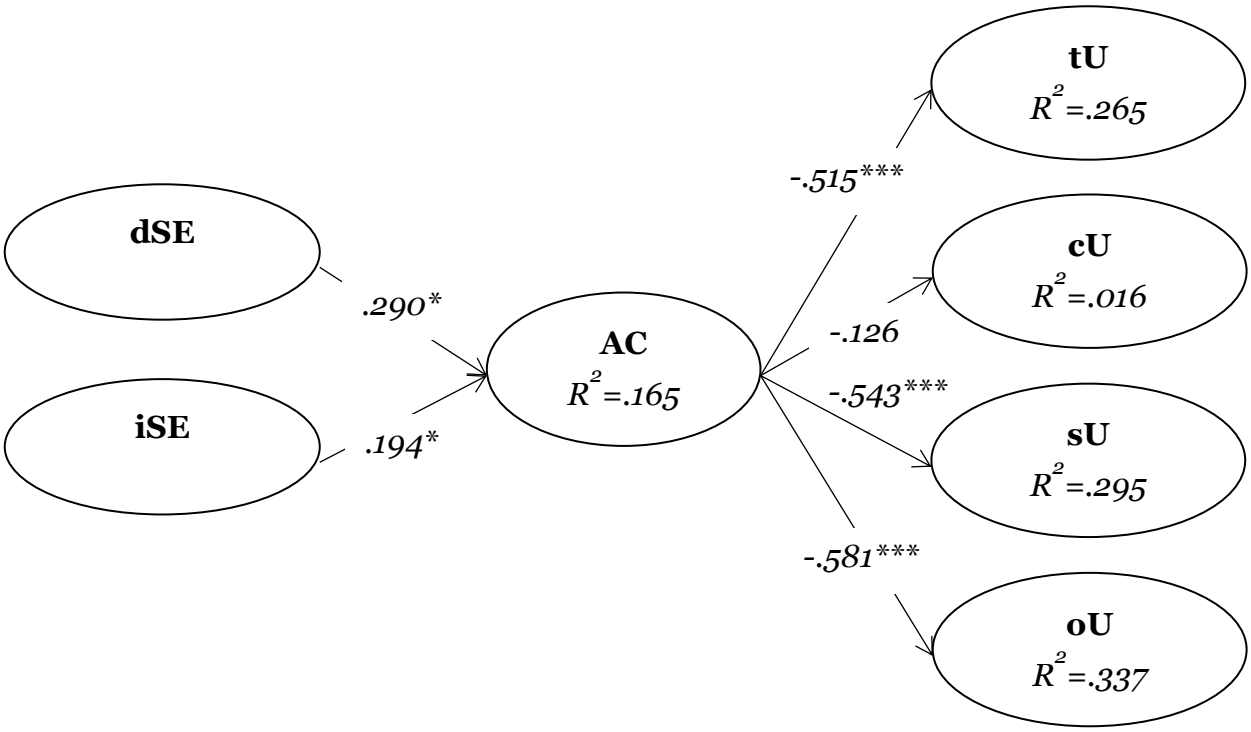


Figure 12: Results H2-H7 Model

* Indicates significant path: *p<0.1, **p<0.05, ***p<0.001

The assessment of the predictive power of the model was performed in the same manner as described above: the PLS (default, path) and bootstrapping (5,000 subsamples, path) were calculated, and the collinearity, path coefficients, their significance levels and R^2 were analyzed. Collinearity was not an issue (VIFs below 5) and the results of the path coefficients and R^2 values can be found in Figure 12.

Apart from the direct effects, the indirect effects are of great relevance for this study. These indirect effects can be found in the following table for each path.

Table 8: Indirect Effects H2-H7 Model

Path	**Path coefficient**	**P-value**
dSE -> AC -> cU	-0,036	0,384
iSE -> AC -> cU	-0,024	0,504
dSE -> AC -> oU	-0,168	0,005
iSE -> AC -> oU	-0,113	0,066
dSE -> AC -> sU	-0,157	0,003
iSE -> AC -> sU	-0,105	0,082
dSE -> AC -> tU	-0,149	0,008
iSE -> AC -> tU	-0,100	0,073

5.5 Discussion

Table 9 provides evidence of which hypotheses are supported or not supported. The support of H1 indicates that the reduction of uncertainty through stakeholder engagement can only be achieved indirectly through the mediation

of absorptive capacity. This shows the need for entrepreneurial organizations to not only engage with their stakeholders, but to also increase their absorptive capacity if they want to reduce uncertainty. An organization might have high engagement with its stakeholders, but might not have the absorptive capacity to exploit the information provided by hence; hence it might be unable to reduce uncertainty. The acceptance of H2 demonstrates that both supercategories of stakeholders are vital for the increase of absorptive capacity. The partial support of H3 shows that abortive capacity reduces technological, social and organizational uncertainty. However, this statement is not supported for commercial uncertainty. The same is true for H4; the results indicate that engagement with indirect and direct stakeholders, both fully mediated by absorptive capacity, reduces technological, social and organizational uncertainty, but not commercial uncertainty.

Regarding the difference in relevance regarding reducing the uncertainty of both direct and indirect stakeholders (H5-H7), it is clear that technological and social uncertainty is reduced mainly by direct stakeholders. As for commercial uncertainty, neither of the two paths is significant; hence, such a statement cannot be supported. Putting these results in a broader context, it is logical that technological uncertainty is reduced mainly by direct stakeholders such as employees and business partners, because they are the ones often involved in the technological aspects of DTD. Although H5 is not supported, the results indicate that indirect stakeholders play a significant role in the reduction of social uncertainty and thus support the Hall and Martin's (2005) proposition that there is the need to focus on indirect stakeholders in DTD to reduce social uncertainty, because such technologies might have controversial and widespread social and environmental implications. In general, the results

demonstrate the vital role stakeholders play in reducing uncertainty during innovation processes. However, this can be achieved only when the information exchanged in such engagement processes can be absorbed by the organizations; hence, the abortive capacity of organizations is another vital construct.

In general, the effect sizes, significance levels and R^2 values indicate a good model fit. However, this is not true for commercial uncertainty. With the effect not being significant and a low R^2 value (.016), model fit might be problematic here. Because R^2 is a statistical measure of how close the data are to the fitted regression line, the low value indicates that the chosen independent variables were not well suited to predict the dependent variable. Both significance level and low R^2 indicate that the hypothesized influence of absorptive capacity on commercial uncertainty does not exist. However, one should not draw this conclusion due to the fact that the other three types of uncertainty are significantly reduced by absorptive capacity. Moreover, there is no strong theoretical argument to support the notion that a higher ability to assimilate, process and exploit external information (absorptive capacity) should not help organizations to also reduce commercial uncertainty. Examining the results report for the outer weights of the bootstrapping, it becomes evident that the standard deviation for the three indicators constructing commercial uncertainty were high (CU_COMP: .635, CU_DEMAND: .555, CU_PRICE: .598), showing evidence for a poor representation of the modelled construct through the measured indicators, leading to poor model fit for the commercial uncertainty construct.

Table 9: Results of Hypotheses Tests

Hypothesis	Path/Expectation	Path coefficient	Support
H1: The influence of SE on U is indirect/fully mediated by AC.	SE → AC → U SE → U	-.252** -.259	Support
H2: iSE and dSE increase AC.	dSE → AC iSE → AC	.290** .194**	Support
H3: AC reduces all four types of U.	AC → tU AC → cU AC → sU AC → oU	-.515*** -.126 -.543*** -.581***	Partial support (not for cU)
H4: iSE and dSE indirectly reduce all four types of U.	dSE → AC → cU iSE → AC → cU dSE → AC → oU iSE → AC → oU dSE → AC → sU iSE → AC → sU dSE → AC → tU iSE → AC → tU	-.036 -.024 -.168** -.113* -.157** -.105* -.149** -.100*	Partial support (not for cU)
H5: Societal uncertainty is mainly reduced by iSE.	iSE → AC → sU < dSE → AC → sU	-.105* > -.157**	No support
H6: Technological uncertainty is mainly reduced by dSE.	dSE → AC → tU < iSE → AC → tU	-.149** < -.100*	Support
H7: Commercial uncertainty is mainly reduced by dSE	dSE → AC → cU < iSE → AC → cU	-.036 < -.024	No support (paths n.s.)

* Indicates significant path: *p<0.1, **p<0.05, ***p<0.001

A general point of improvement of the model fit, from a purely number-driven, empirical perspective, might be found in the optimization of the formative factors and their indicators, for example, through indicator elimination. However, it should be emphasized that "[i]ndicator elimination - by whatever means - should not be divorced from conceptual considerations when a formative measurement model is involved" (Diamantopoulos and Winklhofer 2018, p. 273). Moreover, this study is to be understood as an exploratory approach to modelling the different types of stakeholder engagement and uncertainty. Their relation (absorptive capacity is already an established modelled factor) and its high relevance has been demonstrated. Still, there is potential for future research, for example, in refining indicators and constructs or exploring additional indicators to grantee optimized model fit. Furthermore, it might be worth exploring additional constructs that represent supplementary types of uncertainty in this context. For example, in his literature review Jalonen (2012) also identified other categories of uncertainty. However, this study was explicitly focused on DTD and on the inclusion of social uncertainty, which plays a crucial role in this context. Thus, the focus was on the four categories of uncertainty identified by Hall and Martin (2005) and Hall et al. (2014).

Some researchers might argue that the response rate of this study was unacceptable (Mangione 1995). However, one might also argue that the "key point is to recognize and acknowledge the implications of the possible limitations of a low response rate" (Bryman 2016, p. 235). With that in mind it is argued that the low response rate has no implications for the quality of the data or the study. An indicator that supports this argument is the demographics of the respondents, which demonstrate an extremely high quality of data (more

than 69% of the participants were CEOs/Founders and 23% top-level managers) and that the right target group was reached.

Because the data was collected for all constructs at the same time using the same method, common-method bias is a relevant topic to be addressed. It refers to a distortion of measurement results that occurs when respondents are both the source of the exogenous variable and the endogenous variable. For example, respondents can draw conclusions from the questionnaire about the underlying hypotheses and adjust their responses accordingly. The discussion regarding how to identify and reduce common-method bias has been taking place for more than two decades, but most ex-post approaches have been shown to be insufficient (Richardson et al. 2008). The most effective way to address common-method bias is to use an ex-ante approach, such as collecting data using different methods or sources or at different points in time (Podsakoff et al. 2003). If this is not possible (e.g. due to a lack of resources), it can also be addressed to some degree in the design of the questionnaire by including reverse-scored items and a variety of scales to reduce acquiescence (Podsakoff et al. 2003). The latter was done in this study. Several items were reverse-coded and various ordinal scales were used (a seven-point Likert scale for measuring uncertainty and absorptive capacity and a six-point scale developed by Frey et al. (2006) for measuring stakeholder engagement). As PLS-SEM is robust against measurement error, the use of ordinal indicators is commonly accepted (Henseler et al. 2012).

Due to its explorative character, this study pioneered empirical research at the intersection of stakeholder theory and uncertainty research, opening a path for much future research potential, such as sectoral (as outlined in the preliminary results report; see Annex IV) and regional comparison studies, which were not

performable in the context of this study. Hair et al. (2017b) define two criteria for estimating the minimum sample size (which number is greater): 1) 10 times the largest number of formative indicators used to measure a single construct, or 2) 10 times the largest number of structural paths directed at a particular construct in the structural model. For the model used in this study, 1) applies and indicates that a minimum of 60 cases are required for performing PLS-SEM analysis (largest number of formative indicators is 6), not allowing for group comparison on a regional or sectoral level due to a lack of cases per group. However, the data from this study can be used as springboard for future studies addressing such research questions.

6 CONCLUSION

6.1 Summary

The dissertation demonstrates that RI, with its premise of early stakeholder engagement in the innovation process, is of immense relevance to entrepreneurial organizations, especially with regard to uncertainties in DTD.

Starting from the general research question:

> Q1: How is RI related to the field of entrepreneurship and how can it be operationalized?

Part 1 of this dissertation pioneered the connection of RI and entrepreneurship research. Therefore, the differing interpretations of RI were explored and three core aspects, namely design innovation, normative ends and collaborative reflection were illustrated. After laying out this RI scheme, the notion of

entrepreneurship was scrutinized in the light of this scheme and a theoretical framework was outlined that indicated how to integrate normative ends and collaborative reflection into the entrepreneurial process (the design process transforming opportunity into innovation). The first chapter especially emphasized the potential of collaboration to enable organizations to take normative aspects into account, and thus to moderate the entrepreneurial process to make it more inclusive and its outcome more sustainable and societally desirable. After exploring the operationalization of RI and its relation to the concept of sustainable development on a conceptual level, an empirical perspective on operationalization strategies for RI in practice was adopted. The perspectives of industry representatives from the advanced biotechnology sector that were presented at a multi-stakeholder workshop of the SYNENERGENE project were analyzed. All representatives had a strong focus on collaboration, reflecting the need for mutual exchange and stakeholder engagement. Although, this might be a valuable goal, it was argued that there might be a major driver for such an endeavor in disruptive technology development processes. The past has shown that products based on emerging technologies have often not been accepted, partly due to highly critical attitudes and campaigns by CSOs against emerging technologies such as synthetic biology. A better understanding of the needs and concerns of society could help entrepreneurial organizations engaged in DTD to avoid throwbacks. However, it is not only organizations dealing with emerging technologies that could benefit from the collaborative RI approach. In general, it can contribute to gaining new ideas and knowledge. Nevertheless, it plays a crucial role for DTD, which are associated with high levels of uncertainty.

In general, part 1 of this dissertation outlines a potential role of RI in entrepreneurship research and potential connection points. Furthermore, it describes the operationalization strategies of RI in entrepreneurial organizations on a conceptual level and in practice, with a particular focus on stakeholder engagement as the key element. Moreover, the vital role of stakeholders and their possible influence on the uncertainty of innovation processes are detailed.

Part 2 of the dissertation comprised a closer look at the role of stakeholder engagement in RI. Utilizing a 'confirm and discover' mixed-methods approach, particular attention was paid to stakeholders' engagement in DTD in the field of advanced biotechnology. A qualitative interview approach was utilized to answer the second research question:

> Q2: What role do stakeholders play in entrepreneurial organizations during the disruptive technology development process?

Therefore, the role of stakeholders for RI was scrutinized more closely. This study was located at the intersection of stakeholder theory, entrepreneurship and innovation. The literature at this intersection emphasizes the relevance of the RI approach for firms active in the field of disruptive technology development and identifies the reduction of uncertainty as a core driver of stakeholder engagement activities. The role of stakeholders in the reduction of uncertainties in entrepreneurial organizations engaged in disruptive technology development was examined in relation to four categories of uncertainty - technological, commercial, social and organizational uncertainty. The analysis of in-depth interviews with representatives, who at the time were holding key positions in nine differing SMEs and start-ups active in the field of

advanced biotechnology, yielded insights into the role of various stakeholders, which were grouped into the two supercategories of direct and indirect stakeholders, with respect to the reduction of uncertainty. The main outcomes of the analysis are the following statements:

a) Stakeholder engagement reduces uncertainty
b) It is mainly direct stakeholders that help to reduce technological uncertainty
c) It is mainly direct stakeholders that help to reduce commercial uncertainty
d) It is mainly indirect stakeholders that help to reduce social uncertainty

The interviewees saw a strong connection between the engagement of stakeholders and the reduction of uncertainty. In addition, it became evident that the main benefit of stakeholder engagement for firms active in advanced biotechnology was the exchange of information. Stakeholder engagement was therefore seen as an effective way to acquire information and reduce uncertainty. Moreover, the need to focus on indirect stakeholders in disruptive technology development processes to reduce social uncertainty was emphasized, because such technologies might be controversial.

The insights gained from this qualitative, interview-based research approach were subsequently used to develop hypotheses and a quantitative study was conducted to test them and to answer research question number three:

> Q3: How does stakeholder engagement influence the uncertainty of disruptive technology development processes at entrepreneurial organizations?

Based on an additional, rigorous literature review of the four categories of uncertainty and the inclusion of the concept of knowledge transfer, represented by absorptive capacity, the following hypotheses were developed:

H1: The influence of SE on U is fully mediated by AC.

H2: iSE and dSE increase AC.

H3: AC reduces all four types of U.

H4: iSE and dSE indirectly reduce all four types of U.

H5: Societal uncertainty is reduced mainly by indirect SE.

H6: Technological uncertainty is reduced mainly by direct SE.

H7: Commercial uncertainty is reduced mainly by direct SE.

Two models were established to test these hypotheses. Data was collected using an online questionnaire that catered to the biotechnology sector (the Biotechgate database was used for targeted and traceable dissemination). In total, 119 questionnaires were completed. More than 69% of the participants were CEOs/Founders and 23% were top-level managers, which indicates the high quality of the data. By using SmartPLS, the models were implemented and the hypotheses tested.

The validation of H1 demonstrates that the reduction of uncertainty through stakeholder engagement can be attained only indirectly, with absorptive capacity acting as a mediator. This indicates the need for entrepreneurial organizations to not only engage with their stakeholders, but also to increase their absorptive capacity where possible. The results relating to H2 indicate that both stakeholder supercategories are vital to increasing absorptive

capacity, through which technological, social and organizational uncertainty can be reduced (partial support for H3 - for commercial uncertainty, this is not evidenced). The results demonstrate that indirect stakeholders play a significant role in the reduction of social uncertainty and thus support the proposition of Hall and Martin (2005). They suggest that there is a need to focus on indirect stakeholders in DTD to reduce social uncertainty due to their possible controversial implications.

Generally speaking, part 2 of this dissertation demonstrates the vital role of stakeholders in reducing uncertainty during innovation processes. However, this is attained only when the information exchanged in such engagement processes can be absorbed by the organizations. Hence, absorptive capacity is a supplementary vital construct.

6.2 Contribution & Implications

The specific contributions and implications are included in the discussions in each chapter. In general, the dissertation contributes to the discourse on the operationalization of RI in an entrepreneurial context in theory and practice, for which there is a large research gap in RI literature. In addition, part 1 pioneered the introduction of RI into entrepreneurship research.

Besides these strongly RI-related contributions, the dissertation, especially part 2, also moves research forward at the intersection of stakeholder theory and uncertainty in entrepreneurial organizations, on both a qualitative and quantitative level. With its exploratory, mixed method character the dissertation not only answers highly relevant research questions with academic rigor but also outlines several avenues for future research.

6.3 Concluding Remarks

This dissertation comprised an examination of the concept of RI in the context of entrepreneurship research. With a specific focus on collaboration, or more precisely stakeholder engagement, a theoretical framework was developed that united both domains. Although the boundaries between RI and emerging concepts in the entrepreneurial context, such as sustainable entrepreneurship, are blurred, RI can have major impacts on entrepreneurship research. Integrating collaboration as a key dimension constitutes a shift in perspectives: from the conventional technocratic technology-push and demand-pull perspectives towards a "collaboratively shaping-of-the-future" point of view.

The explorative theoretical and empirical research approach of part 1 sharpens the understanding of RI in business and economics research and shows the potential of RI for business and economics research, and vice versa. It was demonstrated that stakeholder engagement plays a crucial role in the implementation of RI in entrepreneurial organizations. From the RI perspective, this is of specific interest, because stakeholder engagement is a promising tool to reduce, *inter alia*, impact-related uncertainties connected with DTD.

The further examination of the relation between stakeholder engagement and uncertainty in DTD in entrepreneurial organizations described in part 2 was conducted using an empirical approach. Part 2, which consisted of one qualitative and one quantitative study, confirmed that stakeholder engagement played a vital role in the reduction of uncertainty in DTD. The interview study indicated that indirect stakeholders play an especially important role with respect to social uncertainty. Stakeholder engagement activities can help,

especially with regard to assessing social and environmental impacts, to reduce uncertainty in DTD processes. Hence this study shows that stakeholder engagement can have a significant influence on the uncertainty of innovation processes, especially for entrepreneurial organizations that are producing disruptive technologies.

With its explorative character, the quantitative study pioneered empirical research at the intersection of stakeholder theory and uncertainty research. It demonstrated the vital role of stakeholders in reducing uncertainty during innovation processes in DTD. However, this can be achieved only when the information exchanged in engagement processes can be absorbed by the organizations; hence, absorptive capacity is another vital construct.

To conclude, it is worthwhile returning to Stilgoe et al. (2013), who argue that RI "means taking care of the future through collective stewardship of science and innovation in the present" (Stilgoe et al. 2013, p. 1570), to emphasize the importance of collaborative reflection to reduce uncertainties connected with the technological innovation process and thus to take care of the future.

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ANNEX

I. Interview Guidelines

Hello Mr/Mrs [placeholder], my name is Karsten Bolz and I am working at the Karlsruhe Institute of Technology. I am doing my PhD in cooperation with the Schumpeter School of Business and Economics at the University of Wuppertal in which I research entrepreneurial processes.

I am very thankful for your participation today. With the interview, I hope to gain a better understanding of how organizations engage with stakeholders. Therefore, your insights and practical experiences from your daily work are very useful for my research. The interview will take about 60 minutes.

The interview will be recorded for later analysis. Is this ok for you?

The interview is structured according to my research, but we are open to discuss topics you find relevant as well. I want to start with a section in which you say some words about yourself.

Demographics

Q: Could you please say some words about yourself, your position in the organization and the history you have with the organization?

Q: In which way are you involved in the development and implementation of new ventures or products of your organization?

Q: In which way is your organization contributing to a sustainable

development, if you think about economic, social and environmental sustainability?

Responsible Innovation

Q: Responsible innovation is becoming a prominent term in the context of emerging technologies [and you name it on your webpage]. What do you understand under this term and what would you say are its main components?

Q: How do/would you operationalize responsible innovation within your company and how does/would it influence your processes, especially regarding the search, evaluation and implementation of new products or ventures?

Stakeholder Mapping

One key element of Responsible innovation is stakeholder engagement.

Q: Who are key stakeholders for your organization and how close would you describe the relationship to them in general?

Q: How would you describe the general role of these stakeholders for your organization and why is it important to engage with them?

Q: What is the overall goal of the engagement with different stakeholders?

Entrepreneurial Process

In this section I want to go more into detail on the role of stakeholders during the process from the discovery of an opportunity to the final product/service.

Q: What was your most successful product or service you implemented or brought into market?

Q: If you think about this product, who of your stakeholders were involved in the search for the opportunity, its conceptualization and its implementation and how did they influence the process?

Q: How would you describe the influence of the different stakeholders on sustainability goals of your organization (Economy, Ecology, Society)? Would you say that the engagement with stakeholders make your processes and products or services more sustainable?

Uncertainty

Q: Engaging with stakeholders leads to an exchange of information. How does this reduce uncertainties of your processes?

Q: Thinking of scientific, technical, and engineering hurdles which stakeholders help to overcome these and how does this work?

Q: Which stakeholders help to evaluate the commercial feasibility of your products?

Q: Which stakeholders help to assess social and environmental impacts and consequences of your products and operations and how do they do this?

Q: How do you manage to capture the benefits of the innovation within your organization and which stakeholders help to do so?

Q: In which phase do stakeholders help to reduce uncertainty?

Q: What is most important for good stakeholder engagement and how did this help to make your project more successful?

Barriers and Drivers

Q: What are the benefits for your organization to engage stakeholders in the different phases of the process?

Q: What are barriers for stakeholder engagement?

Q: Are there stakeholders you explicitly do not want to engage with?

Conflicting Goals

Q: Being responsible and economically successful is often stated to be conflicting goals. What are your thoughts on this? Would you give up some of your company's profitability to better align your operations with societal needs?

Conclusion

We have now reached the end of our interview. Do you have anything additional that you would like to add that we did not cover so far or do you have any general questions or comments?

- Do you know other SMEs or start-ups that I could interview and to which you may already have contact? Or maybe you also have some stakeholders in mind that could be interesting for my research?
- I sent you the declaration of anonymization beforehand and would ask you to name your preferred degree of anonymization.

In the next few weeks, I will analyze the results of all interviews. Would it be ok for you if I would send you a follow-up e-Mail asking for some additional input? You are welcome to contact me at any time about my research and results. After

publication I am happy to provide the analysis to you and your organization.

Thank you again for your participation in today's interview! I highly appreciate and value your input and perspectives.

II. Declaration of Anonymization

I, Karsten Bolz, hereby declare that

- personalized data (audio files, transcripts and questionnaires) will be stored secured by password and separately from contact details (name and address). The audio files will only be forwarded for professional transcription. Only I and project staff will have access to contact details.
- all your data and information will be anonymized for publication in a way you can choose:
    a) Your name and/or affiliation can be named and direct citation is allowed
    b) Direct citation is allowed without naming your name and/or affiliation
    c) Only indirect citation is allowed; no naming of your name and/or affiliation

I will ask you for your chosen degree of anonymization at the end of the interview and respect your decision while processing and analyzing the data.

With participating in the interview you comply with the use of your data for publications and presentations under the conditions of anonymization above.

Yours sincerely,

Karsten Bolz

III. Factors used in the Structure Equation Model

Factor	Item	Measurement
Stakeholder engagement (SE)		Stakeholders often play a vital role for companies, but there are variations in the intensity of engagement. Some stakeholders are more important than others. If you think of your organization how would you rate the intensity of stakeholder engagement? (0 No interaction at all, 1 Networking, 2 Cooperation, 3 Coordination, 4 Coalition, 5 Collaboration).
Direct SE	SE_EMP	Employees
	SE_CUST	Customers
	SE_INVEST	Investors, shareholders, financial institutions
	SE_PART	Business partners, suppliers, advisors
Indirect SE	SE_COMM	Local communities
	SE_GOVERN	Governmental organizations, regulators
	SE_COMP	Competitors
	SE_MEDIA	Media
	SE_NGO	NGOs, activists
	SE_RESEARCH	Universities, research institutes
Uncertainty		Below you can find several statements regarding important technological, commercial, societal and organizational aspects of innovation processes in biotech companies. To what extent do you agree/disagree with these statements in the context of your organization? (1 = strongly disagree, 7 = strongly agree)
Tech. Uncert.	TU_FEASI	At an early stage of the development cycle we already know if the technology/product development will be technologically feasible. [R]
	TU_USE	It is very difficult to predict how useful our technology/product will be for us in the future.
	TU_FUNCT	Already at an early stage of the development cycle we can describe the function of new technologies/products that we develop in detail. [R]
	TU_QUALITY	Already at an early stage of the development cycle we can make precise statements about the quality of new technologies/products. [R]
	TU_SKILLS	We often use external skills/competences for the development of our technology/products.
	TU_KNOW	Our technology is a ""well-developed science,"" i.e., there is a well-developed body of scientific know-how, there are many well-known cause and effect relationships and the predictive state-of-the-art is very high. [R]
Comm. Uncert.	CU_DEMAND	In our sector it is difficult to forecast changes in the needs and demands of customers.
	CU_COMP	It is impossible to forecast market competition.
	CU_PRICE	It is difficult to forecast price developments of needed materials/resources in our sector.

	Soc. Uncert.	SU_IMPACTS	We systematically assess impacts of our technology/product on society and are very much aware of such impacts. [R]
		SU_EXTERN	We adapt our strategy regularly to compensate external pressure.
		SU_EOU	Users/Customers need intense training to be able to use our technology/product.
		SU_ACCEPT	Our technology/products have a very high acceptance rate within society (not only with end users). [R]
	Organ. Uncert.	OU_IP	We follow a strong IP (intellectual property) protection policy in filing patents to prevent duplication and secure royalty income. [R]
		OU_SECRET	All employees are legally bound to follow our secrecy policy. [R]
		OU_TIME	Compared to competitors we have a short lead time which allows us a short time to market. [R]
		OU_CURVE	We move quickly down the learning curve compared to competitors. [R]
		OU_SERVICE	Compared to competitors we offer extraordinary sales and service quality. [R]
Knowledge transfer			Below you can find several statements related to the role of knowledge within organizations. If you think of your organization, to what extent do you agree or disagree? (1 = strongly disagree, 7 = strongly agree)
7	Absorptive capacity	AC_LANG	Our employees have a common language regarding our technology/products.
		AC_VISION	We have a clear vision of what we are trying to achieve through the acquisition of external knowledge.
		AC_STATE	We have information on the state-of-the-art of available external knowledge.
		AC_ROLES	Our organization has a clear division of roles and responsibilities.
		AC_SKILLS	We have all necessary skills to gain and use external knowledge (e.g. networking, high market awareness, usefulness and demand of/for information).
		AC_TECH	We have the technical competence to absorb new knowledge (e.g. knowledge management tools, recording and storing of knowledge, knowledge sharing platforms).
		AC_MANAGE	We have the managerial competence to absorb new knowledge (e.g. regular internal and external meetings, high information exchange, clear process structures).
		AC_EXPLOIT	It is well known who can best exploit new information within our organization.
		AC_SOLVE	It is well known who can help solve problems within our organization.

R: reverse-coded

IV. Preliminary Results Report

Results Report - Biotechnology Survey 2018

Author: Karsten Bolz

Contact: Karsten Bolz

karsten.bolz@kit.edu

Version: May 2018

Disclaimer: This is a preliminary results report with the purpose to grant early access to the findings to survey participants and hence is written in a non-academic style. It has not been peer reviewed.

Introduction

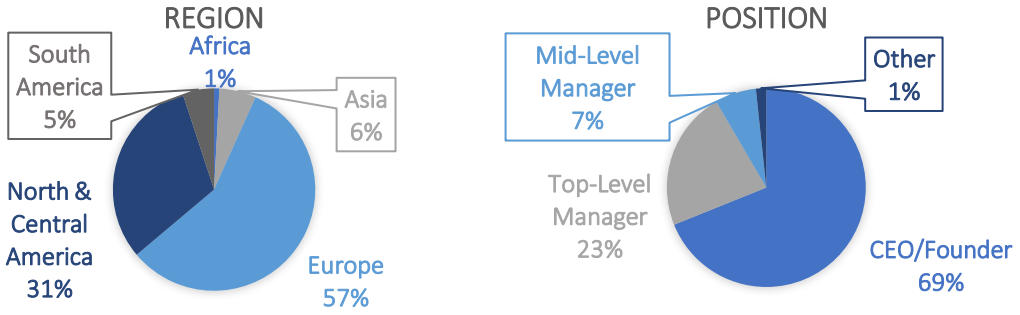
Due to its high level of innovativeness the biotechnology sector is characterized by uncertainty. In theory the engagement with stakeholders can help to reduce such uncertainty through the exchange of information. The goal of this study is to further examine this relation on an empirical basis. The appurtenant survey was done in the context of my PhD at the University of Wuppertal in collaboration with the Karlsruhe Institute of Technology in Germany and focused on stakeholder engagement activities and various topics regarding technological, commercial, societal and organizational aspects of innovation processes as well as on the quantification of the absorptive capacity of organizations. The survey was anonymous by design and hosted on the renowned SoSci Survey platform with servers based in Germany.

This results report presents preliminary descriptive data to grant early access to the findings to survey participants. However, it has not been peer review, is not suitable for publication and does not allow statements regarding causal relations between stakeholder engagement, uncertainty and absorptive capacity. Such causal relations will be explored through a SEM (structural equation modelling) analysis of the data. The results of this SEM analysis will be published in a scientific journal and shared with the survey participants afterwards. Howsoever this report already indicates the high relevance of the study for practitioners and academics.

Focusing on various subsectors of the biotech industry this survey allows for subsector specific insights; on the extend these subsectors interact with stakeholders, are characterized by uncertainty and the magnitude of subsector specific absorptive capacity. These three aspects structure this results report followed by an outlook. However, the report takes a look on the demographic characteristics of the sample first.

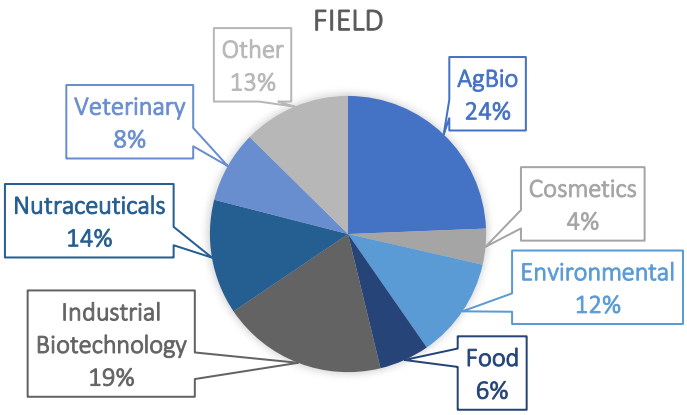
Demographics

In total 119 questionnaires were completed without any missing data. The following charts give an overview of the characteristics of the participants in the survey.



It becomes evident that the majority of the participants were based in Europe (57 %) and North and Central America (31 %). An indicator which shows a very high quality of the data is that over 69 % of the participants were CEOs/Founders and 23 % top-level managers which is of high relevance for this study as it examines general management aspects.

The biotech subsectors in which the organizations of the participants are primarily active are shown in the following figure.



The three biggest subsectors represented are Agricultural Biotechnology (AgBio) with 24 %, Industrial Biotechnology with 19 % and Nutraceuticals with 14 %.

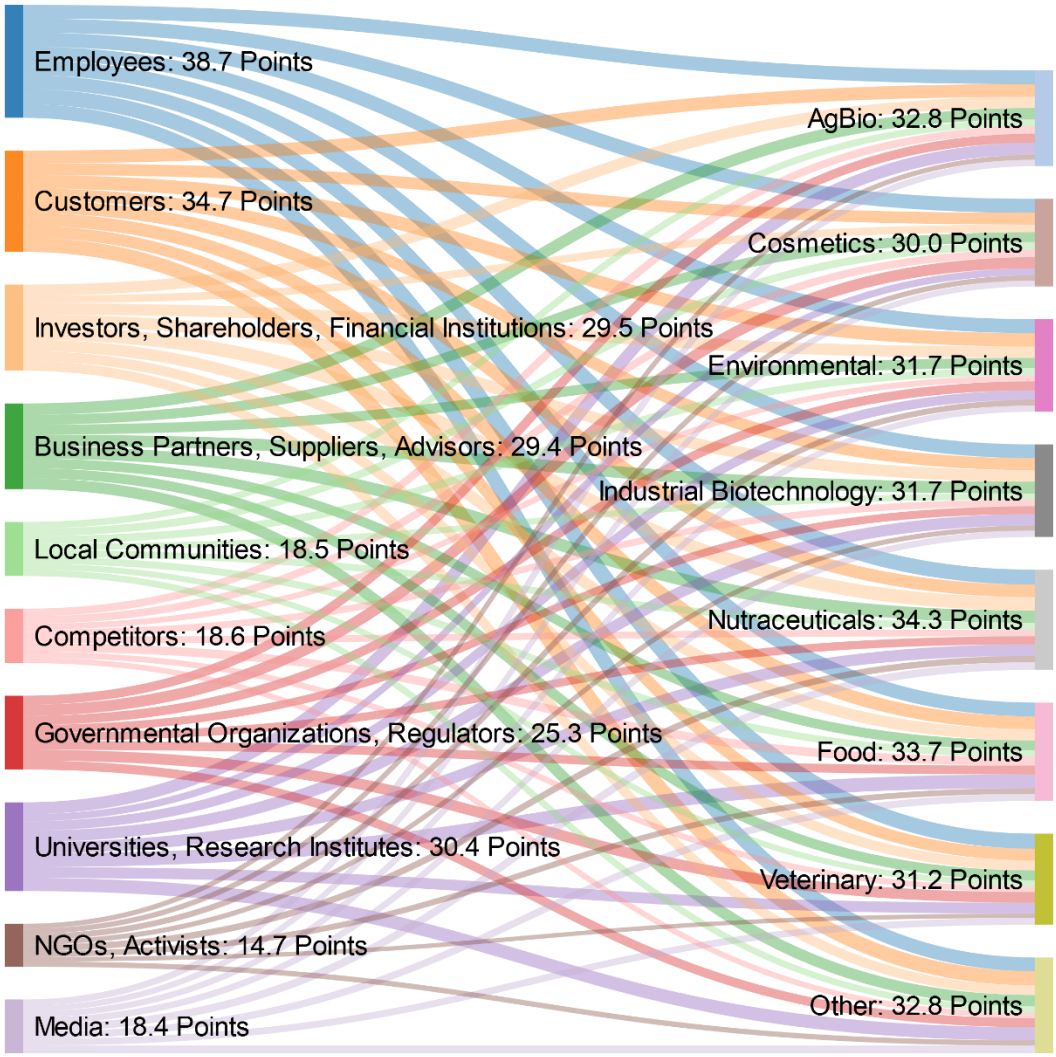
Whereas the sectors represented in the sample of participants is highly heterogeneous the size of the organizations represented by participants is highly homogenous as 90 % fall under the definition of SMEs by the European Commission[10].

Stakeholder Engagement

Literature indicates that stakeholders can be seen as a source of knowledge and information which can help to reduce uncertainty. The stakeholder engagement activities were measured by items asking for the intensity with which the organization engages with the stakeholder groups. Therefore a 6-scale metric to measure interactions between partners was used (No interaction at all, Networking, Cooperation, Coordination, Coalition, Collaboration).

The results for the intensity of stakeholder engagement activities for the various subsectors can be found in the following figure. It shows the various stakeholder groups on the left and the biotech subsectors on the right. The lines in between the stakeholder groups and the subsectors illustrate the engagement activity and their thickness the intensity of such. In addition, points indicate (qualitatively) the intensity of engagement activities; e.g., the Nutraceuticals subsector has the highest intensity of stakeholder engagement activities (34.3 points), followed by the Food subsector (33.7 points).

[10] Staff headcount < 250 **AND** (Turnover ≤ € 50 m **OR** balance sheet total ≤ € 43 m).



It becomes evident, that besides minor variations between the subsectors, employees and customers are the most important stakeholder groups for the biotech sector in general, whereas the NGOs, activists group only play a minor role.

Uncertainty

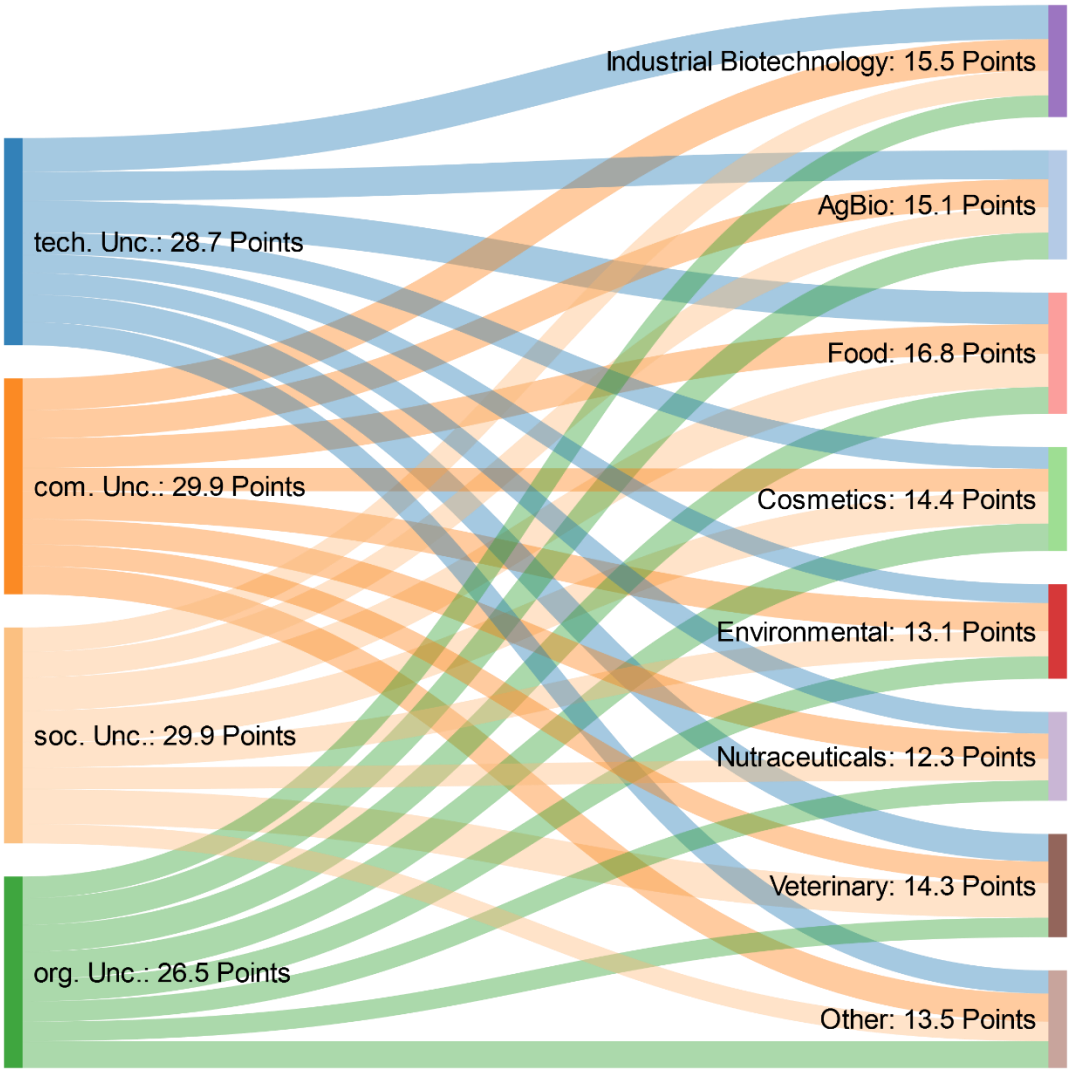
Uncertainty is an inherent part of disruptive technologies such as biotechnology. However, it is important to understand the various aspects of uncertainty to be able to mitigate such.

This study differentiates between four categories of uncertainty:

- Technological uncertainty - concerns overcoming scientific, technical, and engineering hurdles
- Commercial uncertainty - is about whether the new technology can compete successfully in the marketplace
- Social uncertainty - concerns the societal impact on or from society, legitimization and acceptance of the technology
- Organizational uncertainty - is about whether an organization is able to capture the benefits of the technology

These four categories of uncertainty were measured with a 7-point Likert scale asking for the extend of agreement with statements regarding technological, commercial, societal and organizational aspects of innovation processes.

The variations of the four uncertainty categories for each biotech subsectors are illustrated in the following figure.



The diagram shows the four categories of uncertainty on the left and the biotech subsectors on the right. The lines in between (qualitatively) illustrate the magnitude of uncertainty in the respective subsector (thickness of the line); e.g.:

- Social uncertainty is high in the Food, Cosmetics and Veterinary subsectors compared to other subsectors.
- Technological uncertainty is high in the Industrial Biotechnology, AgBio and Food subsectors compared to other subsectors.

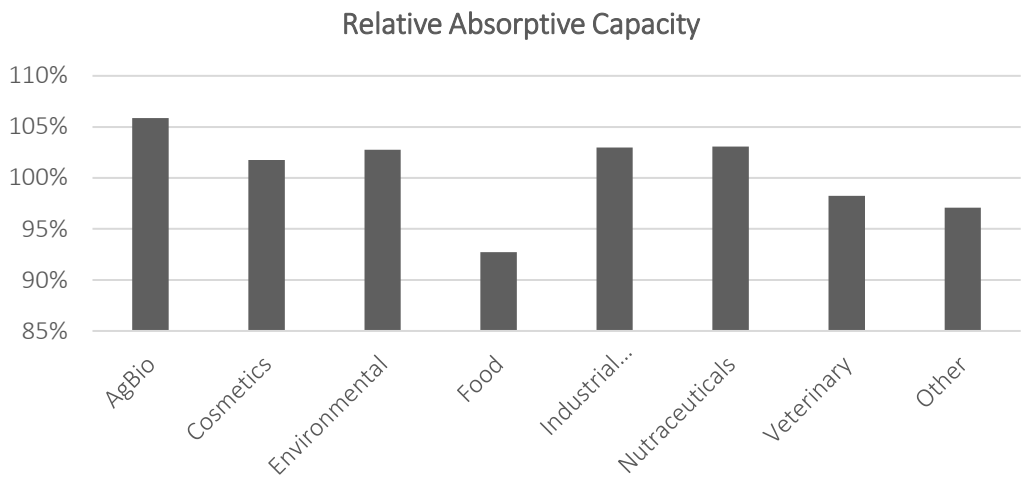
In addition, points indicate the (qualitative) magnitude of the uncertainty categories and the level of uncertainty for the subsectors (e.g., the highest uncertainty can be found in the Food subsector – 16.8 points).

Absorptive Capacity

The concept of absorptive capacity defines an organizations ability to value, assimilate, and apply new knowledge. It consists of four subsets of dimensions: acquisition (identification and acquisition of valuable external knowledge); assimilation (effective assessment, processing and understanding of newly acquired external knowledge); transformation (capability to combine acquired knowledge and existing related knowledge) and exploitation (incorporating acquired knowledge into operations).

This shows that absorptive capacity can be seen as a key competence for innovating organizations to reduce uncertainty; they need to be able incorporate external knowledge and use it to their benefit.

The absorptive capacity was measured with a 7-point Likert scale asking for the extend of agreement with statements regarding an organizations ability to value, assimilate, and apply new knowledge.

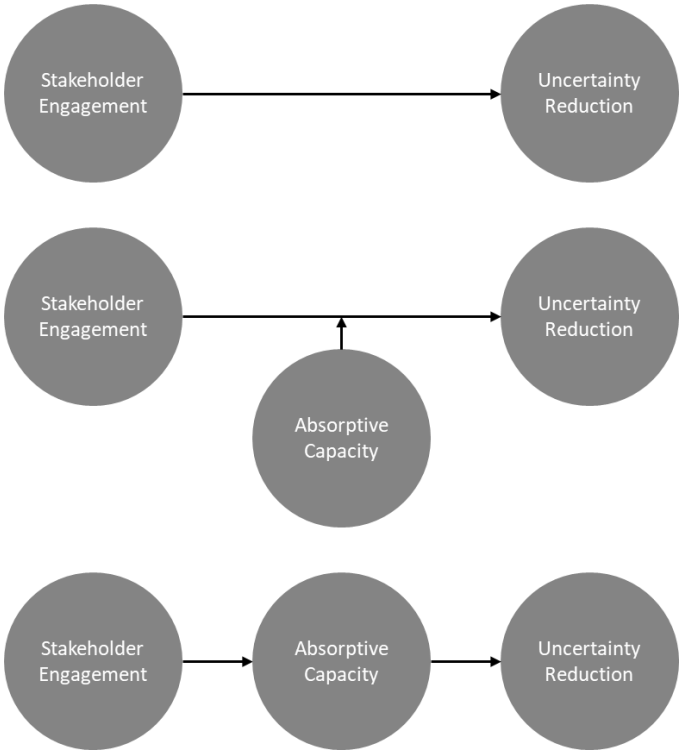


The chart above shows the relative absorptive capacity of the various biotech subsectors (100 % = mean over all subsectors).

It becomes evident that the AgBio subsector has the highest absorptive capacity (106 %) and the Food subsector the lowest (93 %) compared to the mean over all subsectors.

Outlook & Implications

The descriptive analysis of the data provides unique insights into the biotech sector but is limited regarding allowing for evidence of the relations between stakeholder engagement activities, uncertainty and absorptive capacity. For the examination of such relations the data will be analyzed using a SEM approach. The results of this detailed analysis will be published in a scientific journal at a later stage. The most important causal relations that will be analyzed are outlined in the following figure.



In general, it is hypothesized that stakeholder engagement activities reduce uncertainty (top). An additional hypothesis is that absorptive capacity either moderates this causal relation (mid) or even mediates it (bottom).

Such casual relations might have strong practical implications which can help companies active in disruptive technology fields such as biotechnology to adapt their organizational strategy allowing for a reduction of uncertainty through a targeted engagement of stakeholders.

However, the engagement of stakeholders might not be sufficient to reduce uncertainty per se. Without the necessary ability to value, assimilate, and apply new knowledge (absorptive capacity) organizations might not be able to exploit through stakeholder engagement provided information. Such a case might qualitatively be made for the Food subsector. The Food subsector has the 2nd highest intensity of stakeholder engagement activities (33.7 points) but is

characterized by the highest uncertainty (16.8 points). One reasoning for this contradiction might lie in the low absorptive capacity of the subsector (lowest compared to other subsectors – 93 %).

The preliminary results only allow for careful assumptions regarding such causal relations and implications but build the basis for SEM which will allow a detailed analysis. Howsoever they already indicate the high relevance of this study for practitioners and academics alike.

Acknowledgement

I want to thank all participants of the survey who were willing to provide crucial information and share their insights. Without such high quality of information and data this study would not have been possible.

In addition, I want to thank all persons and institutions that provided feedback to improve the survey and the overall quality of the study as well as funding for database and software access.