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Participatory Ethics in Biotech Research Decisions

Identifying Barriers to the Adoption and Implementation of Participatory Decision Making in the Biotech Industry

by

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Abstract:

Today, the biotech industry faces severe stakeholder conflict due to a prevalent science-push paradigm. Participatory concepts offer an alternative to the current mode of stakeholder interaction. The established approaches, Community-based Participatory Research and Participatory Action Research, however, feature substantial shortcomings. By acknowledging these, Participatory Research Ethics (PRE) has been developed as a new framework. With its focus on ethics in research it is thought to facilitate the transition to stakeholder-oriented biotech organisations. A literature review and an explorative study point towards key benefits and barriers of the concept. Findings indicate that scepticism and suspicion against stakeholder inclusion, missing capabilities, management challenges and a negative stakeholder perception towards biotechnological advances are major barriers to the adoption of PRE. To overcome these, a step-by-step strategy was proposed. While it has been concluded that PRE and connected barriers require further investigation, the research makes an important contribution to literature on participatory research.

Key Words: Stakeholder Participation, Social Innovation, Participatory Research Ethics

JEL classification: O320, O330, O350

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1 Introduction

In the biotechnology industry, stakeholders are frequently concerned with ethics (Wolfenbarger & Phifer 2007, Sagar et al. 2000). Respective debates, however, are mostly isolated from science (see Wallace 2005, Mnyusiwalla et al. 2003). Ethical sense-making efforts within the emerging field of bioethics have been made regarding biotechnology practices and products (e.g. Macklin 2003, Kon 2009). However, neither do researchers from science contribute to such philosophical discussions (e.g. Wallace 2005), nor appear research decisions to be questioned at an earlier stage (see Shohet 2004).

A notable gap between science and ethics becomes visible (Mnyusiwalla et al. 2003). Related to this is institutions' perception in the biotech sector that public concerns form an inconvenient concomitant of scientific innovation (see Levitt 2003). This view has recently been contrasted by participatory approaches that target open dialogue with stakeholders. The relatively new concepts of Participatory Action Research (PAR) (Minkler et al. 2002, Whyte 1991) and Community-Based Participatory Research (CBPR) (Hawley et al. 2014, Mckee et al. 2012, Hicks et al. 2013) support this movement and provide insights to benefits and challenges.

2 The Status Quo of Ethics in Biotech Research Decisions

Biotech research is typically characterised by high investments and bureaucracy (DiMasi & Grabowski 2007, Shohet 2004). Organisations in the industry are obliged to meet standards and go through long testing procedures to get approval for new methods or products (DiMasi & Grabowski 2007, Khilji et al. 2006). High initial costs and uncertain sales make it difficult to get a return on research investments (see Shohet 2004). To protect the latter, strong control and secrecy are employed, leading to a comparatively closed research (e.g. Joly 2010, Martin 2000).

Research decision making in the biotech industry appears to be under-investigated. High secrecy and a strong focus on protection of discoveries via intellectual property rights (Joly 2010, Bernauer & Meins 2003, Zucker & Darby 1996) offer an explanation for the absent disclosure of information.

Nevertheless, literature on entrepreneurship reveals relevant factors in biotech research decisions. One critical aspect is the availability of funding (O'Neill & Hopkins 2012). Capital sources can be private or public (O'Neill & Hopkins 2012), resulting in different stakeholder groups. While shareholder interest may influence research in private organisations (Huggett 2012), the strive for governmental funding is guiding academic research (Beaudry & Allaoui 2012, Teirlinck & Spithoven 2012). Furthermore, research decisions are usually based on value evaluations to identify opportunities and markets (Siegel & Renko 2012, Onetti et al. 2010). Above, O'Neill & Hopkins (2012) identified three recent trends that presumably drive biotech research. First, the revolution of information due to IT advancements, second, a boom in investments and third, a revolution in the industrial organisation (O'Neill & Hopkins 2012). Especially the investment boom may explain why research decision making does not receive much attention since the relative abundance of capital can be presumed to diminish sense-making in research decisions. Moreover, it can be argued that research in biosciences is relatively detached from the market (e.g. Khilji et al. 2006).

The industry shows a clear science push attitude (Khilji et al. 2006, Renko et al. 2005, Shohet 2004). Braunschweig (2000) ascertains the ignorance of non-economic factors in the industry and states that the efficiency-aiming, single-factor strategy has been misleading and ineffective, connected to socially undesirable outcomes

(MacDonald 2004, Alston et al. 1998). Apparently, the industry lacks information regarding stakeholder concerns as reactions and opinions of stakeholders remain uncertain where there is little interaction with them (Braunschweig 2000).

Research outcomes are rather communicated afterwards. Osseweijer (2006) states that a one-way communication from science to public is often applied. She calls this a "deficit model" which is insufficient as response to public concerns. In the model, opposing views are considered dysfunctional, even between scientists (Osseweijer 2006). Contrasting, Osseweijer (2006) discusses a more contextual model that focuses on dialogue and exchange relations with the public. Her work supports the hypothesis of an industry paradigm in biotech, slowly opening up towards systemic approaches of ethical decision making. Accordingly, De Cock Buning et al. (2008) proclaim a "new phase of relating societal perspectives to technological developments"[p.9].

The present role of ethics in research appears to be linked to industry paradigms. Ethics are often considered a dysfunctional burden (see Levitt 2003). The over-reliance on economic factors for a return on investment is paired with the belief in pure science (e.g. Shohet 2004).

Two research clusters are connected to intensive, ethical discussions with stakeholders: Genetic engineering (including agricultural food) and biomedicine (Kidman 2009, Savadori et al. 2004, Cahill 2003). Genetic engineering is accompanied by a peculiar strong criticism and a higher perceived risk by the public where it is related to food and agriculture (Savadori et al. 2004, Kidman 2009). Complex issues are also prevalent in gene therapy and embryonic stem cell research, comprising the question for limitations regarding the use of samples and transgenic animals (Mackie et al. 2006). These issues overlap with ethical concerns in the biomedical sector where animal testing is listed next to moral issues regarding drug pricing and the use of personal genetic information (Mackie et al. 2006). The control of pharmaceuticals, guaranteeing patient rights and an adequate pricing for patients are have further shown to be sensitive issues (Finegold & Moser 2006).

Perceived direct benefits can, however, change the public's opinion about biotech research (Kidman 2009). It is equally important to take the general context into account in which research decisions are made. De Cock Buning et al. (2008) refer to a multi-stakeholder context and stress the embeddedness of biotechnology companies. Stakeholders may thus be directly or indirectly affected by an organisation's decisions (see De Cock Buning et al. 2008). Savadori et al. (2004) name harm to humans and harm to the environment as risk aspects of biotech decisions. The decisive impact of biotechnological products on death and life underlines that ethics are directly connected to the industry (see Finegold & Moser 2006). It can therefore be argued that research decisions always involve an ethical and social dimension besides economic or financial ones (Finegold & Moser 2006).

Authors increasingly stress the relevance for the industry to include ethics in operations and to enter dialogue with people having a stake (De Cock Buning et al. 2008, Godard et al. 2004, Macaulay et al. 1999). They espouse a long-term orientation and consider public support and trust as important determinants for success. However, newer communication approaches for ethics are yet to be implemented in many companies. Osseweijer (2006) explains that strategies for the implementation of open communication models are often unknown by researchers, and participatory designs may appear more expensive than one-way communications. In fact, it is has been widely recognised that exchange relations with stakeholders are less costly in the long-run (e.g. De Cock Buning et al. 2008). As a conclusion from Braunschweig's work (2000), this may be ascribed to reduced uncertainty in biotech research. Godard et al. (2004) equally state that community consultation diminishes the uncertainty of research benefits and risks.

Nowadays, biotech organisations often limit public participation in science to ethical debates beyond research (Wallace 2005, Abels 2002). Bioethics have focussed on a debate of philosophical stances with limited impact on biosciences and its research (e.g. Gert et al. 2006). Consequent gaps between ethical reasoning and science are present (Mnyusiwalla et al. 2003, De Cock Buning et al. 2008). Ethics are perceived as a tool to commercialise products De Cock Buning et al. (2008) or to meet legal requirements instead of a way to justify decisions (Finegold & Moser 2006). Linked practices are posteriori justifications and one-way communications to stakeholders (Osseweijer 2006).

Finegold & Moser (2006) observed that little is known about how biotech organisations deal with ethical issues. They examined how companies value and include ethics in different business aspects. Findings revealed that companies include ethics in their vision or mission and develop codes of conduct, but pay little attention to ethical decision making. Compliance with regulations and legal standards represented organisations' only justification for ethical engagement. The majority of firms in the study did not employ stakeholder participation and only 9 out of 29 addressed research ethics. Together with a low response rate of 31 percent, results clearly indicate the industry's disinterest in ethics (Finegold & Moser 2006). Finegold & Moser (2006) comment that the industry should start behaving ethically instead of pursuing a strategy of "legal compliance"[p.290] and recommend a more proactive approach to ethics, allowing to prevent legal restrictions in the long-term.

Pidgeon et al. (2005), suggest surveys as a tool for public participation prior to commercialisation. However, biotech organisations could easily perceive a risk in public opinion since investment decisions in research would be challenged after they have been made. An a-priori approach to participation in ethics, taking place during research decision-making, appears thus to be more solid.

Braunschweig (2000) suggests a wider focus for priority setting in research, with larger amounts of information in research decisions and stakeholders who are able to express their views. Mnyusiwalla et al. (2003) emphasise that cooperation with the public at an earlier stage could positively contribute to close the gap between ethics and science. Elwood (2007) accomplishes the argumentation with the distinction between institutional and participatory ethics. Whereas institutional ethics, assigned to the biotech sector, are linked to unfavourable bureaucratic practices and objectivism, participatory ethics acknowledge contextual variations of ethical reasoning.

The current practice in biotech research affects the relationship between organisations and their stakeholders. Non-transparency has led to distrust by the public, against biotechnology (Wallace 2005) while studies revealed that transparency affects trust in a direct manner (Wallace 2005, De Cock Buning et al. 2008). Some incidents have strengthened the public's scepticism against biotech (e.g Zallen 2000).

Where the public seizes no opportunities to influence biotechnological outcomes, opposition and protest are logical ways to get a voice and to shift government's attention to the industry. The case of Monsanto's genetic modified organisms (GMO) food strategy gives an example how the public's desire to express disagreement can become a worldwide movement (e.g. Weissman 2004, Bernauer & Meins 2003). The company's behaviour has frequently been doubted to be ethical (e.g. Anderson 2017, Klein 2017). At the same time, its claim to "Feed the world" (Oosthuizen 2017) connotes ethical intensions. There are multiple lessons that should be learned from that case. First, ethical intentions are insufficient to build public trust. Second, credibility in ethics is connected to the degree that ethical missions are actually translated into the company culture and practices. Third, ethical intensions may raise the need for ethical discussions. In the case of Monsanto, the company motto values the combat of hunger over possible long-term environmental impacts of genetic modified food. It can, however, be criticised that the actual problem is the increasing world population (Goldin 2014). Monsanto missed the chance

to discuss these views with stakeholders. The company carries on with its practices, risking to be sabotaged by the public and government laws. Today, genetic modified organisms or food (GMO's) are banned from many European states (Bernauer & Meins 2003, Gaskell et al. 2000) as biotech companies failed to find a compromise with European governments (see Bernauer & Meins 2003).

The debate between science, governments and the public is in an impasse (De Cock Buning et al. 2008, Brownsword & Caulfield 2006) and the isolation of science from ethics and politics (Abels 2002) has led to regulating policies. What can be observed equals a catch-up game with governments trying to ensure protection for their societies, however, always far behind biotech developments (see Cahill 2003). States are increasingly concerned with loosing this race of ethical sense-making, often expecting negative consequences of biotechnological developments (Larijani & Zahedi 2007, Knoppers & Isasi 2006).

It is often referred to "biosafety" when approaching the protection of citizen (McLean et al. 2002, Glover 2003). Glover (2003) argues that the expression of "biosafety" pertains to "regulatory issues" that aspire to reach general international standards through harmonisation and normalisation. Practices connected to the term of "biotechnology" are considered more open and inclusive, allowing ethical sense-making through participation in a specific local or national context. With a subjectivist lens, Glover (2003) assesses "biosafety" as an inadequate policy practice which fails to respond to contextual differences and consequently causes disagreements between politics and the public.

Higher regulation levels seem to be tied to in-transparency and resulting fears which presumably form strong motives to restrict biotech research and practices. This is highlighted by the emergence of speculative ethics which aim to predict scientific developments to outpace biotechnology in ethical reasoning (Nordmann & Rip 2009).

Reed et al. (2006) expound that safety regulations affect biotech investments detrimentally due to mounting costs of testing and compliance checks. By means of participatory research, safety issues could be discussed in the forehand, whilst circumventing expensive efforts to respond to regulations.

3 Towards Participatory Ethics in Biotech Research

To this point, it has been argued that when neglecting ethics, biotech companies face the disadvantages of higher regulation and opposition levels, uncertain research investment success and a potentially unmet demand due to a lack of public acceptance (see De Cock Buning et al. 2008, Shohet 2004). Accordingly, De Cock Buning et al. (2008) declare that traditional research decision making in biotechnology has lost its legitimacy.

Participatory research (PR) approaches offer a different role for ethics (Table 1). They embrace stakeholder involvement in research decisions and thereby pursue an a-priori approach to communication. Minkler et al. (2002) consider discussions of ethical concerns to be more constructive in PR approaches and Elwood (2007) claims that weaknesses of traditional, institutional ethics can be overcome by reflectivity and collaboration, resulting in a more sound ethical research basis.

With a stance of critical theory, Blumenthal (2011) names empowerment and ethics as central motives of PR. Ethnographic views build a further rationale for PR with the acknowledgement of situationally specific ethics (Elwood 2007) and the subsequent need for organisations to be flexible and responsive.

Authors name collaboration, education and action as properties of PR (also see Minkler et al. 2002) whilst it is presumed to occur in a long-term partnership between researchers and communities. As a major research objective, achieving research consent often concerns all steps from goal-setting to the evaluation of research results. Results can be local, regarding the structural situation and knowledge gains in communities, and are simultaneously transferable where methods and frameworks are developed (Macaulay et al. 1999).

The access to a broader knowledge base for stakeholders results in the empowerment of those (Blumenthal 2011, Elwood 2007) which consequently allows them to make informed choices (De Cock Buning et al. 2008). Following the approach of Bartlett & Ghoshal (1990), this possibility for local adaptation of research could enhance meeting local demands (see De Cock Buning et al. 2008). Stakeholder cooperation may therefore constitute a competitive advantage. These aspects exhibit the potential of PR to close existent information gaps between science and stakeholders (see De Cock Buning et al. 2008) and thus to reduce the uncertainty of public acceptance and trust (see Hawley et al. 2014, Resnik & Kennedy 2010). As researchers may get valuable feedback and access to local resources and knowledge (Macaulay et al. 1999), research decisions are presumably better with participating stakeholders (De Cock Buning et al. 2008).

Two predominant approaches exist for the implementation of participatory research. One is participatory action research (PAR), originating from the social sciences and aiming collaboration between professional science researchers and organisations or communities (Minkler et al. 2002, Whyte 1991). It desires to facilitate learning processes on both sides: science and the practice. Practitioners participate in the whole research process up to applied research (Whyte 1991). PAR is viewed as an ongoing process and a method to conduct research. It is based on the assumption that valuable research requires knowledge which can be gained through learning. The latter is viewed as long-term process which is in contrast to the traditional short-term orientation in biotech sciences (Greenwood et al. 1993).

The fusion of local knowledge and expertise within PAR reflects a pragmatic strategy that balances situational differences with objective science. It stresses the link between the elements of PR, being collaboration, action and education (Greenwood et al. 1993). As to that, Minkler et al. (2002) underscore organisations' need to take additional responsibilities such as the promotion of education, communication and engagement.

There are a few shortcomings regarding PAR. First, it has only been applied in social sciences and is yet to be transferred to the biotech sector. Second, it limits stakeholder participation to organisations and communities that apply research. Additional stakeholder groups, however, may be indirectly affected by research. Third, the assumptions within PAR are problematic as science is expected to solve society's problems and empowerment is considered a moral value (Greenwood et al. 1993). Yet, it can be doubted that biotech organisations' would consider applying open approaches due to intrinsic moral perceptions. As previously argued, rather economic, political and social implications of a certain moral (or unmoral) behaviour pose the need for participatory research.

In contrast, community based participatory research (CBPR) is primarily designed to benefit and protect communities which are affected by research (Blumenthal 2011, Mckee et al. 2012, Resnik & Kennedy 2010). Communities are composed of members that share certain characteristics (Banks et al. 2013). Similar to PAR, it combines education with action (Mckee et al. 2012), encompassing a long-term partnership between researchers and communities (Mckee et al. 2012). Yet, the inclusion of participants goes beyond the learning focus in PAR and equality between partners is considered important (Banks et al. 2013). Shared leadership and data ownership are community claims within CBPR (Macaulay et al. 1998). Thereby, communities are enabled to express and promote their interests (Hicks et al. 2013).

	Traditional Research	Participatory Research Approaches
Paradigm	objectivism/ positivism *e.g. Joly 2010, Shohet 2004, Bernauer & Meins 2003, Martin 2000, Zucker & Darby 1996*	ethnographic views/ critical theory *e.g. Blumenthal 2011, Elwood 2007*
Orientation	short-term	long-term
Objectives	- economic: efficiency, ROI e.g. *Shohet 2004* - protection of innovations, research and connected investments for competitive advantage *e.g. Joly 2010, Shohet 2004, Zucker 1996*	- flexibility and responsiveness *e.g. Elwood 2007, Osseweijer 2006* - transparency *e.g. Hawley et al. 2014, Resnik & Kennedy 2010* - public acceptance *e.g. De Cock Buning et al. 2008* - meet a demand in the market *e.g. De Cock Buning et al. 2008*
Role of Ethics	objectively assessable: rules, protocols, codes *e.g. Elwood 2007*	situational/ contextual *e.g. Elwood 2007, Osseweijer 2006*
Dialogue with stakeholders seen as…	dysfunctional/ of no value *e.g. Cahill 2003*	constructive/ meaningful *e.g. Hicks et al. 2013*
Timing of Stakeholder communication	post-research *e.g. Einsiedel 1998*	prior to, during and after research *e.g. Mnyusiwalla/ Singer2003, Braunschweig 2000*
How communication is done	informing, one way communication from science *e.g. Osseweijer 2006*	exchange relations *e.g. Osseweijer 2006*
Science, politics and ethics	science separated from politics and ethics *e.g. Mnyusiwalla/ Singer2003*	integration of politics and ethics into science's decision making *e.g. Elwood 2007, De Cock Buning et al. 2008*

Table 1: Comparing Traditional and Participatory Research

With the focus on communities, stakeholder groups are addressed instead of individuals (Resnik & Kennedy 2010). Education and motivation of communities as keys for the implementation of CBPR correspond with other participatory approaches (Hawley et al. 2014, Mckee et al. 2012). In that respect, it is frequently mentioned that the translation from scientific language into community language, and vice versa, is crucial (see Hicks et al. 2013). Experiences with CBPR demonstrated that community participation could enhance transparency on both sides, resulting in improved scientific knowledge and increased trust towards scientific research in communities (Hawley et al. 2014, Resnik & Kennedy 2010).

It is problematic within CBPR that the understanding of communities is often limited to participant groups albeit some CBPR definitions that also comprise representatives of organisations (see Israel et al. 1998). Communities which are not directly involved in research, yet have an interest in it, may hence, be excluded, connoting the neglect of concerns outside research. As governments and the wider public are, however, important drivers of criticism regarding biotech, it can be argued that neither PAR nor CBPR have solved the catch-up process between governments and biotech organisations.

Additionally, it can be doubted that fully open research will be accepted and implemented in an industry where secrecy and IPR protection play dominant roles. Especially in the case of not yet protected discoveries, contracts and high levels of trust would be needed to ensure secrecy in discussions with stakeholders. Compliant, Hacker (2013) names a "potential loss of control" and missing acceptance of the approach in research as weaknesses of CBPR. Steinsbekk et al. (2013) refer to risks resulting from open, dynamic consent. Research, relying on participants, is considered unfree as communities or individuals may pursue personal interests (Steinsbekk et al. 2013).

The drawbacks of PAR and CBPR form a starting point for a new concept which circumvents the exclusion of relevant stakeholders, the post-decision reasoning in research and the demand for holistic participation. Replacing comprehensive participation by a focus on ethics constitutes an alternative that may promote more effective stakeholder relations since stakeholders can qualitatively contribute to open discussions in ethics. Science is thereby enabled to include ethical concerns when setting research objectives, so that research decisions may become more solid. Meanwhile, the ability to conduct broad research would not be affected which may alleviate the scepticism towards stakeholders.

Elwood (2007) introduces participatory ethics as a way to manage conflicting views and information gaps through the discussion of ethical dilemmas with research participants. As other stakeholders, however, are excluded in this approach, a new term is introduced here: Participatory Research Ethics (PRE). It can be defined as a framework, comprising open dialogue with relevant stakeholders to discuss ethical issues in research decisions. Contrasting other PR approaches (see Table 2), PRE shifts away the focus from research implementation to enable the inclusion of stakeholders prior to the conduction of research. Its objective is slightly different with the aim to guide and inform current and future research as an a priori solution to close the gap between science and ethics or politics. PRE is deployed prior the conduction of research, to increase ethical soundness of research decisions, to prevent regulative reactions from governments and to avoid protest from the public.

Similarly based on the principles of empowerment and collaboration, it yet limits these aspects to ethical considerations in research decisions. While stakeholder education remains a central component, PRE merely intends to create a basic understanding of research, allowing stakeholders to make informed choices. Thus, it simplifies the communication between biotech companies and their external parties. Within PRE stakeholders are asked to participate in debates around what and how research is done rather than being participants or contributors to research. This requires more openness from biotech organisations in terms of research objectives.

Mechanisms and strategies for the interaction and communication with stakeholders, described in established PR approaches, can be expected to be equally valid in the context of research decisions. Regarding, ongoing communications, as suggested by Macaulay et al. (1999) or Minkler et al. (2002) may be more beneficial than case-by-case stakeholder consultation which would supposedly further delay the long research process. Still, additional communication techniques may be necessary to address stakeholder groups that are different from communities or research participants.

PRE's focus on ethics further facilitates stakeholder education and empowerment. Supposedly, it is thus also cheaper to implement than other participatory designs. Discussions of ethics with stakeholders right from the beginning of the research process allow organisations to change negative stakeholder perceptions towards biotechnology. With a subsequently improved reputation, biotech companies are more likely to attract customers, so PRE can ultimately be a source of competitive advantage. Knowledge about customer values, emerging from ethical discussions, may further assist to meet a demand. An improved justification of investment becomes possible with the acknowledgement of stakeholder opinion. Cost advantages can be expected where lobbying or legal expenditures for regulations and prohibitions against biotech are reduced through stakeholder participation. With the adoption of PRE, biotech organisations would thus not only change from a reactive to a proactive stakeholder strategy, but would thereby also face the chance to co-determine stakeholder actions that have been previously uncertain.

	PAR	CBPR	PRE
Originates from	social sciences *e.g. Minkler et al. 2002, Whyte 1991)*	health sector *E.g. Hicks et al. 2013, McKee et al. 2012*	—
Objective of the method	bridging science and practice *e.g. Minkler et al. 2002, Whyte 1991*	benefit and protect communities *e.g. Blumenthal 2011, McKee et al. 2012, Resnik & Kennedy 2010*	- benefit stakeholders and science - bridge gap between science and ethics/ politics
Concerns	all research steps *e.g. Whyte 1991*	all research steps *e.g. McKee et al. 2012*	ethics in the research decision making
Participants	organisations/ communities applying research *e.g. Minkler 2002*	research participants *e.g. Israel et al. 1998*	all stakeholders having an interest
Form of participation	collaboration *e.g. Minkler et al. 2002, Greenwood et al. 1993*	shared leadership and data ownership *e.g. Macaulay et al. 1998*	collaboration in ethical debates
Organisation's motive for adoption	- intrinsic moral values - mutual learning - ensure research application in practice *e.g. Minkler et al. 2002, Greenwood et al. 1993*	- improve trust - mutual learning - increase transparency - benefit communities *e.g. Hawley et al. 2014, Resnik & Kennedy 2010*	- reduce uncertainty - meet demands - avoid negative implications of unmoral behaviour

Table 2: Comparing PAR, CBPR and PRE

However, barriers may impede the PRE implementation (see Table 3). As PRE represents a new approach, literature on established PR approaches served to identify barriers. The rationale for this decision is the fact that barriers of PR approaches are likely to overlap due to industry specifics.

The status quo analysis revealed the barrier of an objectivistic paradigm. A certain scepticism against participatory research approaches can be expected. Contributions from external parties may not be valued beneficial and compliance with protocols and rules may be conceived as sufficient for ethical reasoning (see Elwood 2007). As

discussed previously, fear to loose control over protected research may further be dominant. Especially claims for shared research data (e.g. Burhansstipanov et al. 2005) can be viewed problematic. Even if PRE protects secrecy as a value where it is needed, this fear may hinder the PRE implementation.

A lack of funding represents another striking barrier. Mnyusiwalla et al. (2003) remarks that more funding would be needed to overcome the gap between ethics and science and Hicks et al. (2013) equally mention funding as a major challenge for CBPR in biotech organisations. It is evident that where organisations do not value stakeholder participation, a budget is not likely to be allocated for PRE.

Participatory Research is a time-consuming process that requires additional capacities (Burhansstipanov et al. 2005, Hicks et al. 2013), connected to various management challenges. Processes and protocols, concerning the communication, evaluation and the reporting to funders need to be developed in order to obtain valuable outcomes for research from stakeholder participation (Burhansstipanov et al. 2005, Hicks et al. 2013). The participant selection can further be a challenge and source of conflict which is why it is particularly relevant to consider who is included or excluded (Minkler et al. 2002). Biotech organisations would have to employ a consistent selection strategy. Burhansstipanov et al. (2005) and Blumenthal (2011) suggests to focus on community representatives.

Above, the management of partnerships with stakeholders require mutual respect and trust (Hicks et al. 2013) and can only create value where participants can make informed choices (see Tendulkar et al. 2011). Education and the selection of informed people (Tendulkar et al. 2011) may serve to guarantee this. To get a meaningful partnership, a continuous negotiation of partnerships objectives is key (Hicks et al. 2013). Defining who is responsible and how PRE is strategically implemented may also form further management tasks for a PRE implementation.

Barrier	Description
Scepticism/ Suspicion	- fear to loose control over protected research e.g. *Joly 2010, Bernauer & Meins 2003, Martin 2000, Zucker & Darby 1996* - stakeholder participation seen as dysfunctional *e.g. Cahill 2003*
Lack of funding	- lack of budget for participatory designs *e.g. Mnyusiwalla et al. 2003, Hicks et al. 2013* - lack of time investments *e.g. Burhansstipanov et al. 2005, Hicks et al. 2013*
Status Quo Evaluation	- compliance with rules and protocols considered sufficient *e.g. Elwood 2007*
Missing capabilities	- training in stakeholder communication *e.g. McKee et al. 2012, Minkler et al. 2002* - development of processes and protocols *e.g. Burhansstipanov et al. 2005, Hicks et al. 2013*
Management challenge of PRE implementation	No clarity, remaining questions: - who organises PRE? - who should participate? *see Minkler et al. 2002* - how can PRE be implemented? - how to manage conflict

Table 3: Barriers to the Adoption of Participatory Research Ethics

4 Research Methods

In the first part of this study, we compared participatory approaches and identified barriers to their adoption. The second part is an explorative study, to test identified barriers and to provide insights regarding the feasibility and acceptability of PRE. The literature-based creation of a barrier framework prior to feasibility and acceptability testing of PRE reflects a normative approach to research. Simultaneously, a pragmatic perspective is employed as deductive methods have been used to find present patterns whereas an inductive method is used to acquire evidence and further insights.

As PRE is considerably new and slightly different from other PR designs, an explorative strategy is favourable to test what challenges and obstacles are perceived by people active in the relevant field. Knowledge gaps, regarding biotech decision making processes, have been demonstrated in previous sections and raise the need for in-depth information.

Interviews seem to be a common method of data collection in participatory research approaches (e.g. Minkler et al. 2002, Faridi et al. 2007).As biotechnology experts embody specific information on research decisions and potential ethical reasoning in the industry. Therefore, expert interviews have been chosen as a sampling strategy which allows to obtain in-depth information, to acknowledge the specific context and to explain PRE to participants.

The expert selection has been made in a purposive manner by choosing people active in or with specific knowledge about biotech research processes. For higher representativeness, it has been attempted to maximise the variety of people through different professional roles and organisational forms.

Finding interviewees has been challenging. Three different sources have been used for the interviewee acquisition. First, a social media platform for all kind of users, second, specific forums for biotechnology and third, personal contacts. Posts in biotech forums were the least successful with no replies after multiple attempts and weeks. The other two streams provided 16 relevant contacts. Seven agreed to take part in the research, resulting in a response rate of 43,75%. Although this seems good compared to other related, academic papers (e.g. Osseweijer 2006, Finegold & Moser 2006), the long time that it took to identify these people and missing responses from open posts suggest scepticism against the term of ethics and other perspectives on biotech. Two interviews could only be accessed via a previous interviewee, a fact that further highlights secrecy in the industry.

In the sample (see Table 4), organisation types varied from public or academic research institutions to a startup or entrepreneurial activity. Positions included employees with or without management responsibility, and an entrepreneur whereas roles ranged from researcher and communications manager to professor and entrepreneur. A broad spectrum is therefore provided.

Semi-structured, audio-recorded interviews have been conducted. Three major blocks have been covered, namely research decision making, ethics and PRE, including its barriers. To guarantee informed consent, anonymity and confidentiality, participants had given consent by voluntarily signing a consent form after being provided with an information sheet. All data has been anonymised and interviewees have been named I1-I7, accordingly.

The interview transcripts have been analysed by means of a qualitative content analysis according to Mayring (2000) as it offers two strategies for the application of categories, one being inductive, the other deductive. In this study, the two related processes are merged to accomplish the inductive-deductive research design mentioned above.

Interview Code	Organisation Type	Field	Position	Role
I1	Public Research Institution	Clinical Research	Employee	Clinical Researcher
I2	Startup	Health	Employee in Management	Senior Manager
I3	Public Research Institution	Agricultural Research	Employee	Postdoctoral Researcher
I4	Public Research Institution	Genetics	Employee	Communications Manager
I5	Research Society	Agricultural Research	Employee	Postdoctoral Researcher
I6	Consulting Activity/ Entrepreneurship	Education/ Investments	Entrepreneur/ Board Member in Academia/ Consultant	Independent Lecturer, Investor and Entrepreneur
I7	Academic: University	Education/ Agricultural Research	Employee	Professor and Chairman

Table 4: Sample Description

The first step consists in collating the text material with previously defined barriers, that represent categories. Coding rules state how the text is interpreted towards the categories. In a second step, additional barriers are inductively searched and abstracted. A category application table resulted for every interviews. Additional notes have been taken to cover descriptive aspects.

During coding, categories have been compared, pooled and matched. The strength and occurrence of patterns, also called codes or pattern codes (Saldaña 2016), have been investigated, subsequently. For each interview, the times a pattern was mentioned has been pit against the total number of patterns stated, resulting in a percentage that reflects a share of all patterns which has been taken as an indicator for the strength of a pattern. This method has been based on descriptions by Namey et al. (2008) who recommended an assessment of the frequency for the appraisal of codes' importance.

Flick (2009) and Saldaña (2016) validate the classification of patterns by frequency. In our analysis, a classification rule was posed, considering a share over zero and below five percent as low, one between five and ten as medium and one over ten percent as strong. The numbers one to three were assigned to these strength levels and been put into a table overview.

Keys, signalising the category with an alphabetical letter and the subcategory through a number, have been connected to each pattern. The mean of interview strength numbers has been calculated per pattern and a strength category has been stated accordingly. Considering the importance of relative frequency (Namey et al. 2008) which is the occurrence of codes across cases, the patterns A7, B2, B4, C2, C3, D6, E4, E5, E8, E9, E10, F2, F5, F8 and H have been eliminated as non-representative single case patterns

All categories and the coding agenda were revised afterwards, followed by a second review of the text material in order to obtain the highest possible reliability for the categories and the overall framework, whilst acknowledg-

ing the limited degree of reliability resulting from the small sample size. Conclusively, barrier categories were interpreted in context of the literature and the research question.

5 Findings

5.1 The Biotech Context

The biotech research decision making processes, described by the participants, corresponds with the impression gained in the introductory sections. Five interviewees described them as closed towards other stakeholders, underlined by statements referring to science push and the exclusion of stakeholder valuation and engagement from institutions' priorities. I1 also emphasised that procedures and protocols in the industry can be very bureaucratic which inhibits the initiation of change. I3 revealed that in an academic context, science can be rather uncontrolled as professorships are provided for lifetime and professors are almost free to decide what research is followed. In a commercial context, this isolated science can be challenged by investors or other shareholders who may push it towards ethical considerations (I7). Biotech researchers, by contrast, do not consider ethics as science's responsibility (I3). In the interviews, questions around ethics have not always been answered, a fact, suggesting ignorance against ethical reasoning This has further been highlighted by I5 who stated that ethics are recognised, but not addressed. Some interviewees also referred to a misconception of conflict. I6, for instance said: "whatever you do, someone will be outraged". These views raise the need to consider conflict as natural. Accordingly, the interviewee emphasised the importance of managing conflict rather than only attempting to avoid it.

Yet, some interviewees acknowledged the value of ethics and provided means of improvement. I1 named translational research as an option to engage with non-scientists and I5 considered more value oriented discussions as a possibility to improve discussions around different ethical stances.

I2 and I4 came from organisations employing participatory designs. I2, working in a start-up business environment, ranked the research decision making process in her organisation as open compared to the industry. Processes have been designed around the customer and external stakeholders are included in almost every step, right from the first product designs. Accordingly, the company manages a network of stakeholders, composed of academics, experts, consumers and health professionals.

Findings point to a coherence between the type of research decisions and the openness of a biotechnology company. Interviewees, coming from contexts with more ethically problematic fields like agriculture (I3,I5,I7) or biomedicine (I1) rather described research in their field as closed towards stakeholders. The fields of genetics has meanwhile be more stakeholder-oriented while biotechnology in the health sector even encompassed active stakeholder engagement in our sample.

5.2 Benefits of Stakeholder Participation

The findings yielded more clarity regarding the benefits of participatory design approaches (see Table 5). It is striking that I2 who worked in a stakeholder-friendly context, perceived most benefits. The latter could be summarised in four categories.

First, dialogue with stakeholders provides a feedback function which can be deployed to improve products, services or organisational processes and structures. In contrast to the predominant aim to understand stakeholders (I1,

I3, I4, I7),valuing and using feedback for change and development entrusts an active role to biotech institutions in stakeholder communications. These benefits, however, can apparently only fully be obtained where participation empowers stakeholders; where people "have a voice"[I2, p.3]. Beyond, stakeholders can not only be asked for their needs, but may also take part in testing procedures for reliability and validity feedback (I2).

A second advantage are reduced costs as there is a higher likelihood that people are willing to volunteer for testing without payment after they got empowered (I2). Third, higher standards, for instance regarding ethics can be achieved through mechanisms of exchange with stakeholders (I2). This is intertwined with the forth advantage which is the potential improvement of businesses competitiveness by means of product or service adjustments to stakeholder needs (I2, I3, I6). I2 stated accordingly: "We can't design the best products without talking to people about what they want"(I2, p.5). In addition, I6 and I7 viewed stakeholder engagement as an opportunity to improve the reputation and visibility of scientists or institutions. The fifth advantage is the lower risk, resulting from access to stakeholders that determines the ability to influence or predict stakeholder opinion and reaction (I2).

Benefit	Description
Feedback	- Stakeholders as a valuable source of information (I2, I3, I4, I7)
Lower costs	- Stakeholder become involved without getting monetary compensation (I2)
Higher standards	- Higher standards can be achieved if the biotech industry works together with stakeholders
Increased competitiveness	- Meeting a demand through involvement of stakeholders as customers - Higher visibility - Better reputation
Lower risk	- Predict and determine stakeholder opinion/reaction through interaction with them

Table 5: Benefits of PR

Whereas some institutions perceive the benefits of stakeholder engagement, others still do not. The prevalent strategy is characterised by avoidance of and reaction to suboptimal stakeholder relation. It is referred to this by the aim to reduce negative stakeholder emotions towards science and by the target to prevent opposition and protest. These views pose a solely negative image on stakeholders. Corresponding, relationships and perceived value of engagement are often limited to direct stakeholders who fund research in the institution (I3, I5).

Nevertheless, it should be noted that a substantial part of the interviewees engaged in public relations although this frequently meant spending extra time or effort beyond their work which typically, did not involve these aspects. It is remarkable that mounting degrees regarding the implementation of participatory designs resulted in higher answer rates. All questions have been fully answered in the cases of I2 and I4 as well as in the case of I7 who actively engages with the public. However, frequent questions regarding the topic and uncertainty about answers in all interviews can be associated with a prevailing unawareness of participatory solutions.

5.3 Success Factors for Participatory Designs

Certain conditions facilitate stakeholder participation. Adequate and qualitative stakeholder communication as a requirement has been cited by all interviewees. I2, I3 and I4 argued that stakeholder relations must be considered in the longer term to make them successful. Ongoing discussion with stakeholders (I2, I4) and the way how information is provided and exchanged, form essential aspects. A relaxed environment is seen positively related to success in stakeholder discussions (I5). Finding a commonly agreed level of risks can be a starting point in that respect (I5). According to I3 and I4, information must be reliable, credible, multifaceted and independent. I1 further considers communication to be optimal where it is specific and direct.

I7 stresses the need of a value-oriented discussion, a fact that links to PRE since value-oriented dialogue is likely to involve discussions around ethics which in turn, are thought to be a positive condition for the implementation of participatory designs. By taking I7s notable experience in stakeholder engagement into account, PRE is thus reassured as a valuable approach. Interviewees also highlighted the necessity to understand and respect stakeholders (I7) and to treat them as equals (I2) which points to the empowerment of stakeholders in participation and inclusion. The requirement therefore is do both, inform and include stakeholders (I2). The behaviour of an organisation ultimately influences success of participatory designs. Honesty, transparency and authenticity are connected to positive outcomes (I2, I4, I7). As a prerequisite, I3 names trust which may be build over time when stakeholders become convinced that an organisation behaves in a friendly way towards them. However, funding represents an important constraint that determines the degree to which a participatory approach is adopted (I4).

Above, I6 and I7 set a stakeholder management strategy as crucial condition for the implementation of stakeholder participation. I6 argued that it allows the avoidance of negative stakeholder reactions on the one hand and the management of the same on the other. Proactive behaviour which is viewed critical by I2 equally puts stakeholders into the strategic focus.

5.4 Barriers

Enlightening results could be attained with regards to the identification of barriers. In the deductive category analysis (Table 7), the predefined barrier framework has been tested. Evidence reflected all categories with at least two patterns per category. Scepticism and suspicion (A), often related to the traditional science push, represented the most significant barrier with various patterns. The strongest pattern has been "participation as a means" (A1), which stands for an exclusive valuation of participation only where it serves research objectives. Although the pattern has solely been stated by two interviewees, it has been emphasised through the multiple designation and is therefore considered relevant. The non-valuation of a participatory approach (A2) labelled with medium strength, was cited by six of the seven interviewees, implying that participation was either not valued by the interviewee or the institution, or it has been excluded from the organisation's priorities.

A3 referred to science push and in this case specifically to researchers', institutions' or scientists' opinion that science embodies a superior role, letting it be more capable to decide for the best course of action. Five of seven interviewees have been pertaining to this pattern, letting it appear representative. Moreover, its strength is rated medium which implies that on average, it counted for 5-10% of all patterns in an interview. It is remarkable that I2 and I4 which came from institutions employing a participatory approach did not mention A1 or A3. This may reflect a different reasoning in these organisations which rather registers the potential benefits of stakeholder involvement.

The objective to protect research (A4) seems to be a rather weak barrier, stated only once by two interviewees. Yet, to completely exclude it from the barriers, it might require further investigation. A5 and A6 have been stated by four people and three interviewees respectively, but the frequency of these patterns per interview was low. An underlying uncertainty or scepticism towards the success of inclusive stakeholder designs (A5) may thus be present, which on the contrary, does not seem to be particularly strong.

The separation of ethics and science (A6) equally appears to be a barrier of low strength, but with relevancy for all types of biotech organisations. This also corresponds with the impression that science and ethics are typically separated and perceived as different spheres.

"Hostile stakeholders" as a pattern denotes the assessment of stakeholders as antagonists to science. I5 in particular, mentioned the distribution of misinformation and lies as negative stakeholder attributes. The pattern is medium strong, yet not representative for all interviewees. Still, the negative association of stakeholders by science may be relevant to explain scepticism against stakeholder participation.

Besides patterns of scepticism and suspicion, a clear lack of funding could be observed. The majority of interviewees said that funding for stakeholder engagement is limited. Evidence revealed a lack of dedicated resources in terms of time and efforts, different from the narrow focus on monetary funding. This mirrors the afore-mentioned disinterest in participatory designs which is consequently followed by a lack of resources invested in stakeholder engagement. More importantly, it is to be associated with the need for people in biotech to dedicate time and effort voluntarily if they are willing to change the situation concerning stakeholder relations.

The status quo poses another barrier, regarding established rules, protocols and practices. C1 reflects that the latter are used to cover ethics and stakeholder activities on a minimum level. In defiance of the low strength, five interviewees referred to C1, allotting a certain relevance to it. By contrast, missing linkages to stakeholders (C4), were only cited twice and marked by low strength. Perhaps, this can be ascribed to non-awareness of participatory stakeholder approaches or to prevalent science push structures which hamper external linkages or even the consideration of those.

On the whole, B and C display low pattern strengths. Although a lack of funding in terms of money, time and efforts as well as established structures appear to be obstacles, their overall impact as a barrier is considerably low. Moreover, it can be argued that the availability of funding and present structures are influenced by the attitude that science holds towards stakeholder participation. If the latter is negative, the organisations is unlikely to design its structures, processes or budget schemes for stakeholder participation. Thus, A can be assumed to influence B and C by a positive relationship.

Besides, missing capabilities have shown to be another important issue. Especially knowledge transfer to stakeholders appears to be problematic. This is reflected by a lack of stakeholder education (D3) and the missing translation into stakeholder language (D4) in biotechnology. With a low to medium and medium strength, and an occurrence in four interviews, they form crucial patterns. Another aspect is the missing capability to build processes, protocols and structures for stakeholder participation (D5) which, however only appeared in two interviews and can thus not be considered representative. Nevertheless, the fact that certain structures, and consequently capabilities, are missing is further highlighted by D1 and D2 which demonstrate an underdeveloped advertising and incentive system for stakeholder participation. This again, implies that stakeholders are neither addressed nor valued as contributors.

The third relevant block of barriers in the deductive analysis consists of management challenges. The most significant one is the management of stakeholder communications (E3). It is exceptional that all interviewees referred to this pattern which is why it is considered most reliable and representative of all patterns. Meanwhile, use of adequate language is vital. All other patterns similarly refer to the challenge to correctly interact with stakeholders. The problem of contextual differences (E1) regarding communities or stakeholder groups, lead to variations of the correct way to deal with stakeholders. Language, again, forms an essential factor in that respect. E2, cited by the majority of interviewees, refers to the difficulty to build trust and credibility. Yet, the pattern's relative strength is rather low which may imply that a problem of trust and credibility is acknowledged, but does not necessarily denote a barrier to the adoption of a participatory approach. I5 affirmed this interpretation by saying: "Providing multifaceted information may appear as lobbyism in the beginning, but in the longer term, more credibility can be gained.". Thus, a barrier of mistrust and stakeholder scepticism can be overcome by long-term efforts which have also been mentioned amongst positive conditions for participatory stakeholder designs.

The impediment of interaction with stakeholders (E6) requires biotech organisations to move away from one-directional stakeholder communications. Four interviewees considered this as a hurdle to the implementation of stakeholder participation and together, assigned a medium strength to it which makes it a notable barrier.

The challenge to manage a network of different stakeholder groups (E7) has only been unveiled by three interviewees, a circumstance that may be due to the rare number of cases in which a stakeholder-near approach is adopted. The pattern's low strength may be explained by adjusted structures where stakeholders are included. Still, it might be interesting if the the management of new structures reflects a serious challenge after it has been decided to adopt and conduct stakeholder inclusion.

Supplementary obstacles could be discovered in the inductive category analysis. Pursuant to the management challenges of building trust and credibility as well as to apply adequate language, a distinctive perception of science and research by stakeholders can be observed. This has been exposed as another category of barriers (F). Regarding, three patterns have been found particularly important, all labelled with medium strength. First, the case of stakeholders' negative perception of scientific research (F4) which emerged as the strongest category pattern with five interviewees giving credit to it. Simultaneously, it has clearly intertwined with insufficient or wrong information as well as with fear and disgust as negative emotions. This again, underlines the need for a strong communication strategy and the education of stakeholders. Especially the public as a stakeholder tends to employ a reasoning based emotions which is different from science (F9). This results in a barrier if linkages for the translation of science into stakeholder language, and vice versa, are absent or if a mutual understanding of reasoning is missing. The fact that the majority of interviewees gave reference to this aspect depicts the continuous separation of ethics and science. The claim for security (F6) portrays an influencing factor for stakeholder perception. Evidence indicates that the guarantee of anonymity, confidentiality and product, service or process safety facilitate positive stakeholder perception and trust whereas deficiencies appear as a barrier.

Outstanding are two other patterns, only cited by interviewees coming from organisations with participation in place. On the one hand, they discovered a medium-strong obstacle with the unknowingness of stakeholders (F3), related to negative perception, on the other hand, they adverted to the empowerment of stakeholders (F7). Although the latter has been labelled with low strength, it matches the previous argumentation in favour of stakeholder empowerment.

The benefit that stakeholders perceive with regards to their participation is clearly linked to their motivation to engage (F1). It is not astonishing, that low strength has been assigned to this factor since other interviewees

	Framework		*Evidence*	
Category	**Initial Framework**	**New Framework**	**Strength**	**Stated in X Number of Interviews** *(Total number 7)*
Scepticism/ Suspicion	✓	✓	Medium	6
Lack of funding	✓	✓	Low	7
Status Quo Evaluation	✓	✓	Low	5
Missing Capabilities	✓	✓	Low-Medium	7
Management Challenges	✓	✓	Medium	7
Stakeholder Perception	✗	✓	Medium	7

Table 6: Barrier Framework Revised

unveiled a fundamental stakeholder willingness to have a voice. I2 particularly stressed: "Those [...] want to help because they want to help themselves and they want to help their community.".

The last category contains two patterns of unawareness concerning ethics and participatory designs. A certain degree of unawareness regarding the topic is shown by these patterns, but their frequency and strength make let them appear rather insignificant. Beyond, they can be assumed to be partly enclosed by category A, addressing scepticism and suspicion, which may be caused by unawareness of participatory solutions. Category G is therefore excluded.

None of the single patterns in the two analysis parts has been denoted strong. This may point at multifaceted factors influencing the adoption or implementation of an stakeholder oriented approach. Albeit, it also highlights the need for further empirical evidence. None the less, the aggregation of single patterns to the superordinate categories lifts the lid on relevant barriers which tend to exist in all biotech organisations.

In comparison to the previously defined set of barriers, a new framework is suggested, based on the preceding analysis. It matches the majority of original barriers but has been extended by negative stakeholder participation which has been added as an additional barrier.

6 Discussion and Conclusions

It could be discovered that maintained scepticism and suspicion towards stakeholders as well as a science-push attitude prevent the adoption of a stakeholder-near approach. Many authors, like Martin (2000) and Joly (2010) have referred to this by noting the fear to loose control over protected research in the biotech industry. The interviews showed that stakeholders are neither expected to be valuable contributors nor understood as their reasoning is often different from science. Cahill (2003) in particular, has illuminated the dysfunctionality that the biotech industry associates with stakeholder contribution. The fact that stakeholder groups use contrasting ways of sense-

making is strongly supported by Osseweijer (2006) and Hicks et al. (2013) who also highlighted the subsequent need to communicate and translate between the different layers of reasoning.

Capabilities and structures, needed for the installation of stakeholder inclusion, were found missing. The adequate communication and interaction with stakeholders, appeared as critical factor. Corresponding with Mckee et al. (2012) and Minkler et al. (2002), the results revealed missing capabilities in stakeholder communication.

The negative perception by stakeholders towards science highlighted the current impasse situation, which may only be overcome where the biotech industry changes its behaviour towards stakeholders.

The study offers a new mode of stakeholder relations that is particularly relevant for managers deciding on research and related structures in the biotech industry. PRE has been proven to feature benefits. Organisations with stakeholder participation for ethics are likely to have beneficial relationships to stakeholders and achieve higher standards, increased competitiveness as well as lower costs and risks, consequently.

By putting barriers into a chronological order, a step-to-step strategy for PRE implementation becomes possible, starting with a change of mindset that is required to remove the barrier of science-push. Biotech organisations should attempt to mitigate scepticism and establish conflict management. Secondly, new capabilities need to be build, regarding stakeholder education, communication structures and linkages to stakeholders. The installation of a communication strategy and respective structures constitutes an important milestone. Organisations would equally have to change their behaviour to build credibility and trust when interacting with stakeholders. Facilitating factors are an appropriate language that acknowledges the context and type of stakeholders, transparency and the transfer of knowledge transfer If these conditions are met, the negative perception by stakeholders is likely to be overcome. Yet, to be successful,stakeholder engagement requires not only long-term efforts, resources and management, but also the empowerment of stakeholders by sufficient knowledge that allows them to qualitatively contribute.

In the third place, resources therefore need to be allocated to stakeholder participation to install and maintain it. The employment of a dedicated participation managers may be an option. Forth, capabilities need to be build to deploy PRE efficiently. Employee training in stakeholder communications may be necessary to achieve a qualitative and value-oriented discussion. Biotech organisations will have to widen their pure science focus towards ethical discussions, a task that may require a change of internal structures and reasoning. A crucial aspect is the transfiguration of the reward system as to incentivise stakeholder engagement

Despite, it remains the question for the best approach to participation. In this work, the focus has been on participatory research ethics (PRE) and thus on an inclusion of stakeholders for the discussion of ethical aspects that may arise from research. As participation is yet to be implemented and the mindset continues to be narrow in many cases, definite clues, allowing a comparison of different participatory approaches have been missing. This fact depicts a major shortcoming inherent to this paper. Two arguments emerge from the evidence that rather support an approach like PRE. First, stakeholders, especially the public, seem to be prone to a value-oriented reasoning*. Second, traditional research structures are still strongly established which is reflected by the discussed barrier of scepticism and suspicion. This makes an approach with ethics at the centre seem reasonable for the transition from traditional to participatory approaches as science can be expected to be more willing to agree with a new concept that does not require total openness. Withal, the a priori inclusion of stakeholders for ethics in research decisions allows to create a mutual benefit. Evidence illustrated that stakeholders have an interest in improving their situation. One interviewee stated accordingly: "people are happy to be involved, people are happy to have a voice". This person also elucidated that an inclusion of stakeholders in all steps dilutes the necessity to discuss

ethics since tensions are instantly cleared up. Yet, this strategy can be extremely difficult, as described in section 3. Above, biotech organisations would have to evaluate if they will be able to obtain value from an overarching stakeholder inclusion.

The study also has limitations. With a relatively small sample, it does not allow for generalisations or reliable results. Despite the variety of the sample, large biotech organisations could not be interviewed.This missing industry component constraints the explanatory power of the research. The nature of PRE further points at shortcomings. It has been stated that PR literature is only partially transferable to PRE which complicates research for this new approach. Notwithstanding PRE's focus on research decisions which differs from other PR approaches, barriers have been drawn from literature on those established frameworks which is why the research design may not have been entirely valid to measure barriers for PRE. Above, evidence points towards a potential link between biotech sectors that involve more ethically problematic research decisions and degrees of stakeholder openness. Further research is necessary to test if an approach of PRE is hence appropriate for any kind of biotech research.

To expand the explanatory power of this research, PRE requires further justification. Larger samples need to be investigated regarding the benefits and constraints of PRE as well as the barriers to its implementation. Besides the possibility to conduct further interviews, an experimental study may be suitable to test if PRE can create value in the specific context of biotechnology research.

It needs to be acknowledged that some scientists are beginning to change stakeholder relationships which may indicate an early change in science's stakeholder approach. Yet, they often face the barrier of established structures and mechanisms as well as a missing valuation of their efforts in biotech organisations. It is ultimately the decision of biotech organisations which role in society they want to take. PRE, in that regard has extended the choice by a different, interactive role that contrasts the current mode of stakeholder interaction.

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7 Appendix

7.1 Deductive Category Analysis

Key	Name	Description/Patterns	Strength Level
A	**Scepticism/Suspicion**		
A1	Participation as a Means	- Participation beyond research objectives not valued - Participation not an objective itself, but can serve to fulfil pursue research	Medium-Strong
A2	Participation not considered important	Participation not valued, not a priority	Medium
A3	Science Push	Science seen as superior actor who is assumed to be more capable to decide what's the best course of action	Medium
A4	Protect Research	The protection of research as a concern against stakeholder participation	Low
A5	Scepticism towards Success	Success is not considered to be likely or scepticism regarding the benefit of participatory designs is present	Low
A6	Separation of Ethics and Science	Ethics seen as social science which is not seen in direct connection to science	Low
A8	Hostile Stakeholders	Some stakeholders perceived as being hostile to science: - Spreading misinformation - Telling lies - […]	Medium
B	**Lack of Funding**		
B1	Limited Funding for Stakeholder Participation	Funding for participation of stakeholders is very limited or not available	Low
B3	Investment in Time and Effort	Time and effort are named as critical investment aspects/ barriers	Low
C	**Status Quo Evaluation: Rules, Protocols & Practices**		
C1	Rules, Protocols & Practices for Ethics/Participation	Rules and Protocols are strongly established/ not criticised so that they may represent a barrier to stakeholder approaches	Low
C4	Missing Linkages to Stakeholders	The connection to stakeholders is not established and the ability to connect to them is limited/not present	Low
D	**Missing Capabilities**		
D1	Advertising	Advertising needed to promote participation	Low
D2	Missing incentive system	No incentives present that reward stakeholder engagement	Medium
D3	Missing Stakeholder Education	Stakeholder might have to be trained to increase their involvement	Low-Medium
D4	Translation into Stakeholder Language	Different language used by stakeholders represents a barrier and is not sufficiently translated/ understood by scientists/ researchers in the biotech industry	Medium
D5	Development of Processes/ Protocols/Structures for Stakeholder Participation	Structures for the implementation of participatory approach are missing	Low-Medium
E	**Management Challenges**		
E1	Contextual differences	Communities/Individuals may have different ethical stances Importance of adequate language	Low
E2	Build Trust and Credibility	Trust and credibility are to be built in order to get benefits out of stakeholder involvement	Low
E3	Stakeholder Communication	Adequate communication towards stakeholders considered critical; adequate language important	Medium
E6	Interaction with Stakeholders	Informing stakeholders not sufficient, more active interaction needed	Medium
E7	Managing the Network	Managing the stakeholder network efficiently to get a beneficial outcome out of participatory approach	Low

Patterns eliminated that only occurred in a single case (see appendix): A7, B2, B4, C2, C3, D6, E4, E5, E8, E9, E10, F2, F5, F8, H

Relative Strength calculated by sum of strength number (1,2,3) in positive cases (>0) divided by number of positive cases

Table 7: Deductive Category Analysis

7.2 Inductive Category Analysis

Key	Name	Description/Patterns	Strength Level
F	**Stakeholder Perception**		
F1	People's benefit	Willingness to participate from the perspective of stakeholders depends on the perceived value of participation	Low
F3	Not-knowing	People not informed Connected to ignorance and negative perception	Medium
F4	Negative Perception	Negative Perception of Scientific Research	Medium
F6	Security	Guaranteeing anonymity, confidentiality and product/service/process safety Connected to trust & positive perception	Low-Medium
F7	Having a Voice	Connected to positive perception	Low
F9	Emotional or other different reasoning compared to science	Stakeholder language can be different from science language - Linked to negative perception	Medium
G	**Unawareness**		
G1	Non-awareness of Participatory Solutions	Unawareness regarding the implementation/existing efforts of stakeholder inclusion or in general the possibility to include stakeholders	Low
G2	Non-awareness of ethics	Unawareness/Ignorance of (potential) ethical concerns	Low

Patterns eliminated that only occurred in a single case (see appendix): A7, B2, B4, C2, C3, D6, E4, E5, E8, E9, E10, F2, F5, F8, H

Relative Strength calculated by sum of strength number (1,2,3) in positive cases (>0) divided by number of positive cases

Table 8: Inductive Category Analysis