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Perspectives of COPD patients, publicly funded scientists, and industry representatives on responsibility and stakeholder engagement in drug discovery research

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ABSTRACT

Ensuring societal influence in research and innovation through stakeholder engagement is vital in the Responsible Research and Innovation (RRI) framework. By studying a drug discovery project, we examine how stakeholders can influence drug discovery and development meaningfully. Through semi-structured interviews, we explore: How do patients as potential users of a new drug, the scientists who discover it, and the industry that might develop it, think about responsibility and stakeholder engagement in drug discovery? Most of the responses voiced by our informants about responsibility and stakeholder engagement relate to the broader institutional and political context of health-related innovation, rather than the specific research project. We argue, that in order to make stakeholder engagement work within some forms of drug discovery research, it should be used as a forum for mobilizing political and organizational debate, taking critical dialogues beyond project-specific engagement in innovation.

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Introduction

Taking the broader societal impact of research and innovation (R&I) into account through stakeholder engagement is considered a core element of Responsible Research and Innovation (RRI) (Ribeiro, Smith, and Millar 2017). This broad and contested focus on science-society relations differs from previous approaches contextualizing R&I within broader societal contexts, such as studies on the ethical, legal, and societal implications of science (Åm 2019; Zwart, Landeweerd, and van Rooij 2014). What distinguishes RRI is its emphasis on how stakeholders, including potential product users, can actively influence specific R&I projects (Gerber et al. 2020; Owen, von Schomberg, and Macnaghten 2021). Grounded in the principle of influence, stakeholder engagement

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in RRI has emerged as a solution to navigate complexities arising from conflicting interests and concerns about a product (Kwee, Yaghmaei, and Flipse 2021). In this manner, stakeholder engagement, alongside associated concepts such as public engagement, citizen science, and public deliberation, is gaining prominence as crucial for the legitimacy of scientific endeavors and the generation of socially robust knowledge. However, determining who to include as stakeholders, how to involve them, and how to do so in a way that allows the R&I project to respond to feedback from diverse actors is not straightforward (Felt 2017). Focusing specifically on drug discovery and development, we place this dilemma at the crux of this paper. We explore how patients, scientists, and industry representatives talk about responsibility and stakeholder engagement.

The development of a new drug takes 15–20 years and average costs have been estimated to be between 1.6 and 2.8 billion dollars (Wouters, McKee, and Luyten 2020). Modern drug discovery often starts from a gene or protein associated with a disease and develops a drug candidate through systematic strategies with a desired therapeutic effect (Hughes et al. 2011). We base our article on a drug discovery project that aims to find new antibiotics and new therapies for Chronic Pulmonary Disease (COPD). The scientists in the project have generated promising chemical compounds. The project is multidisciplinary, and builds on computational biology and chemistry, medicinal chemistry, and structural biology. For the Research Council in Norway (RCN), which funded the project, a focus on RRI and science-society relations is a funding criterion. The project is also embedded in the Centre for Digital Life Norway, a context that has previously been studied for its elaborate engagement with the RRI framework (Åm, Solbu, and Sørensen 2021). Norway has adopted concrete measures at a policy level to implement RRI and is consequently of great international relevance when it comes to understanding initiatives to improve science-society relations (Åm 2019; Åm, Solbu, and Sørensen 2021).

Despite funding demands, an academic focus on the application of RRI in the field of drug discovery projects is largely missing from the academic literature (Wang et al. 2021; Yu 2019). Our joint role in the project was to integrate RRI principles into the work conducted. Hence, we found a need to decipher different perspectives on how stakeholder engagement can inform RRI in drug discovery and development in a concrete project setting. Like most biomedical research, drug discovery research is characterized by a high level of technical specificity, uncertainty, and stringent regulatory requirements (Sinha and Vohora 2018). We consider it to be important to explore how drug discovery that is supposed to operate according to the principles of RRI, can – meaningfully – be influenced through stakeholder engagement. Therefore, we seek diverse stakeholders' perspectives on responsibility and stakeholder engagement by asking: How do patients as potential users of a new drug, the scientists who discover it, and the industry that might develop it, think about responsibility and stakeholder engagement in drug discovery research?

RRI, responsibility, and stakeholder engagement

RRI sparks academic debates and influences scientific governance policies worldwide, yet its precise meaning remains elusive (Ribeiro et al. 2018). Concerns of public distrust

ignited the focus on RRI in policies from the European Commission which aimed to enhance research legitimacy, generate societal benefit, maximize research impact and innovation uptake, and stimulate market-driven innovation (Michali and Eleftherakis 2022). Much of the discourse that accompanied the emergence of RRI is informed by the desire to not repeat the 'failures' of the past where new innovations were rejected when it reached the potential users (de Saille 2015). Different ways of operationalizing RRI have emerged, ranging from Value Sensitive Design to the six keys of RRI (ethics, science education, gender equality, open access, governance, and public engagement), and the four dimensions of RRI (anticipation, reflexivity, inclusion and responsiveness) – all involving certain ideals and yet also presenting barriers to reaching those ideals (Timmermans et al. 2020). While RRI has morphed into encompassing everything from increased reflection to foresight of the effects of research and innovation, our focus in this paper is on the wide notion of stakeholder engagement in research. The RRI literature emphasizes a governance approach that involves users, developers and other groups identified as holding stakes in the end product, from the early stages of research to align research with societal values and to continuously anticipate and assess ongoing implications (Braun and Starkbaum 2023).

Research has established that when governance approaches and policy ideas are taken to on-the-ground actors, they can lead to completely different outcomes (Shore, Wright, and Però 2011). Several decades of academic work within the field of Science and Technology Studies (STS) point to the interdependency and co-production between science, innovation, and society (Irwin and Wynne 1996; Jasanoff 2004). This work has helped make sense of the public resistance towards particular forms of biotechnological developments, such as opposition towards genetically modified organisms or synthetic biology, and contributed to the necessity of socializing research through societal engagement. However, much happens when established findings about technoscientific developments are translated (e.g. Callon and Latour 1981) into a 'concept' (RRI) for adoption into funding policies, which in turn demands to be translated into actions and practices. This study builds on research that has focused on how actors within different fields of scientific R&I relate to responsibility and how responsibility is done in practice (Åm 2019; Åm, Solbu, and Sørensen 2021; Davies and Lindvig 2021; Felt 2017; Glerup and Horst 2014; Glerup, Davies, and Horst 2017; Hjorth, van Hove, and Wickson 2017). We aim to provide insights into how societal actors, including previously uninvolved patient groups, engage with responsibility. In this way, we draw on STS approaches that do not take definitions of responsibility for granted but regard them as a multifaceted concept that changes shape and meaning, depending on practices and organizational structures (Davies, Glerup, and Horst 2014). From this perspective, stakeholder engagement represents a particular way of 'responsibilizing' research and addressing societal concerns.

Other concepts such as citizen science, co-creation, public deliberation, and deliberative dialogues also focus on societal influence on science and emerging technologies. 'Public deliberation' predominantly focuses on influencing policy-making processes rather than directly influencing concrete research. Its aim is to involve the broader public in decision-making processes, shaping policies, and fostering societal influence on science and emerging technologies. The rationale behind these efforts is that deliberation is crucial for averting problems, fostering collective action, and enhancing public

trust in decision-making processes. Sideri and Prainsack (2023) argue that science alone cannot determine policy decisions, emphasizing the need for public engagement to understand values and perspectives and promote solidarity. However, the challenges of public deliberation include hierarchical decision-making, fast-paced contexts, and underrepresentation of marginalized groups (Irwin 2006; Wynne 2006).

We do believe that engaging different publics, and notably, responding to concerns voiced during engagement and inclusion activities, is crucial for securing the societal benefit of research and innovation. However, it is not a straightforward endeavor to determine how to do so, especially in highly uncertain, specialized and strictly regulated domains like drug discovery and development. This is why we defined three groups – patients, scientists and industry representatives – whom we interviewed to gain insights into their views on responsibility and their engagement with each other throughout the R&I process, all aimed at enhancing project outcomes.

Methods

All in all, we conducted 37 qualitative, semi-structured interviews from June 2021 through May 2022 with patients, scientists, and industry representatives. We interviewed ten scientists, 19 COPD patients, and eight industry representatives. We chose to interview COPD patients as they were identified in the project as the primary target population for one of the compounds that the scientists were working on. The scientists we interviewed all worked for the drug discovery project. The industry representatives were contacted partly through our network and partly without prior acquaintance.

We asked our interviewees questions related both to their understanding of responsibility in drug discovery and development and about stakeholder engagement. The interviews were subsequently transcribed and uploaded into NVivo, a qualitative data analysis software where the interview material was coded according to two main questions: (1) How do stakeholders talk about responsibility and their concerns? And (2) How do they want to engage with other stakeholders? In line with our theoretical approach, when analyzing the interviews, we use 'responsible' not as a pre-defined concept, but in the same fluid fashion that our interviewees use the concept. It provides insight into how responsibility is understood in multiple ways by the people who might hold stakes in the process and outcome of the drug discovery research. We found that there was a distinction between how each group spoke about their own responsibility, and about the responsibility of others. This is why we divided the first question into two: (1) How do they speak about their own responsibility? And (2) How do they speak about the responsibility of others? We structured the results according to these questions. All information about the participants has been anonymized. The study is approved according to the guidelines presented by University of Copenhagen (journal number: 1988972/4242) and the Research Ethics Council in Norway, assessed by Regionale komiteer for medisinsk og helsefaglig forskningsetikk (journal number: 275584) and conducted in accordance with the General Data Protection Regulation and the Helsinki Declaration. Informed consent was obtained, sometimes through prior e-mail correspondence and at times verbally at the beginning of the interview.

Our choices of how to enroll informants and which questions to ask had a formative influence on the responses we received. As mentioned, scientists were recruited from the

project in which we were concurrently involved. We continuously interacted with them and drew on their knowledge and their concerns from observations in meetings and other formal and informal settings. [Deleted] interviewed them online due to the social-distancing regulations in Denmark which prevented face-to-face meetings in the aftermath of the COVID-19 pandemic. The industry representatives we interviewed were all based in Denmark but operated globally in international markets, including Norway. Interviews were conducted by [deleted] online or at interviewees' offices, depending on their preferences. Patients were recruited from both Denmark and Norway. In Norway, we recruited patients through a professor and medical doctor who had previously enrolled patients in clinical research related to COPD. In Denmark, recruitment was conducted via social media (a Facebook group for COPD patients and a rehabilitation program running in a large city). The COPD patients were diagnosed late in their life and were not active in patient-organizations. The interviews were conducted over the phone with or without video, online or in person, depending on the preferences and health considerations of the participant. We recruited across the neighboring countries for practical reasons and based on the logic that medicine launched in Norway would likely also be launched in other Nordic countries such as Denmark.

Results

In the following section, we share the perspectives of COPD patients, researchers from different disciplines working on the same project, and industry representatives. We present our results from each stakeholder group structured according to three broad questions: How do they talk about their own responsibility? What are their preferences when it comes to engaging with other stakeholders in the R&I process to improve societal influence in drug discovery? How do they talk about the responsibility of other stakeholders?

Patient perspectives

How do patients talk about their own responsibility?

Not surprisingly, the COPD patients we interviewed did not have a ready-made understanding of 'responsible research' as a concept, nor of the process of drug development. Almost none of them had given this topic much thought in advance. People tend to relate to things that matter to them (Cohen and Gianni 2023). Many informants interpreted questions about responsibility as a call for more personal responsibility. COPD is typically caused by exposure to toxic gases or from cigarette smoke, but there are also genetic factors involved (Agustí et al. 2023). This triggered multiple conversations about the responsibility to 'act healthily' and take responsibility for their own ill health.

Patients brought up the question of personal responsibility with varying sentiments, some apologizing for getting the disease while some refused any blame. A 53-year-old woman from Denmark working for an office supply company was willing to embrace more responsibility: 'I'm fine with taking some more responsibility for my own situation,' she remarked without being more specific about how. This perspective echoes discourses on public health in Nordic societies where the notion of responsibility implies that

individuals may have to behave in a certain way to remain healthy (Hågvar and Alnæs 2020). Yet, a recently diagnosed patient living in the suburbs of Copenhagen stated the opposite: 'COPD is not really a "sexy" disease to have, like heart disease for example—many think it's our own fault. But I haven't ever smoked.' She was also speaking in the context of personal responsibility in relation to COPD, however from an angle that links personal responsibility to stigma. The stigma related to having COPD as something 'self-inflicted' has been addressed as a highly problematic tendency observed in medical practice and society (Mathioudakis, Ananth, and Vestbo 2021). These responses clearly show that what responsibility means is modulated by the actors who interpret the word in their own way relative to their own circumstances.

What are patients' preferences when it comes to engaging with other stakeholders in the R&I process to improve societal influence in drug discovery?

When we asked questions about what role respondents wished to have in the context of drug discovery and development, most were unsure about what we meant when the question was phrased in any way that suggested that they have an active role to play. One 67-year-old man from Norway explained: 'I trust the fact that everything is being tested properly and that they know what they're doing.' Several other patients expressed similar sentiments: 'Others take care of these things, and I'm fine with that,' stated another Norwegian man in his 60s who worked as a ticket inspector. Trust has been called the 'Nordic Gold' in a report by the Nordic Council of Ministers (Andreasson 2017). Among the main drivers of this 'gold' the report mentions the reliability of societal institutions, the universality of the welfare state, and the absence of corruption. While we are not attempting to provide a definitive explanation of the origins or essence of trust (cf. Sheikh and Hoeyer 2018), we can see that interviewees' references to trust meant that they did not wish to define their own role in drug discovery and development. Luhmann (1999) argued that trust is a shortcut to social action; trust is needed when we operate in contexts we cannot fully know or scrutinize. He suggests that trust (and distrust) reduce social complexity that otherwise would paralyze our ability to act (Luhmann 1999). In fact, patients did express a basic reluctance towards engaging in any concrete aspect of drug discovery and development, due to their own experienced lack of knowledge.

Scholars have argued that civil society involvements in technical projects are mostly top-down exercises in disguise (Irwin 2001; Joly and Kaufmann 2008). Within the project we worked on, one subject that scientists discussed repeatedly was the mode of delivery of the new drug they wanted to develop for the COPD patients. The question was whether the patients would prefer oral drugs or inhalers once the drug had been developed. While patients had different rationalities – the difficulty of using inhalers properly, the taking up of space in the purse, and so on – most of the patients preferred pills to inhalers. One patient, a retired sailor, remarked, 'We don't know what's best for us, so I […] expect experts to guide us.' This statement highlights how the patient would like to avoid taking decisions or providing input, as he believes that the complexity of drug discovery requires experts to make choices, and that these choices, by default, will be 'responsible.' Another example shows that – to patients – engaging in R&I might seem intimidating. One patient, a job adviser from Denmark said: 'Things are so complex, I don't even know how I should answer you […] I don't have much spare

time to study how my medicine was made' – referring to her own potential engagement in the process of drug development. From her perspective, it did not make sense to even desire influence, given the many obligations she already had in her personal life. However, when we phrased questions about more concrete ways of contributing to research, i.e. data sharing or clinical trial participation, it came across less laborious, even for the job adviser: 'I can talk about those things [side effects] and they can use the data on me, for developing better treatment,' she explained. Thus, the specificity of the type of engagement that was required was important for the patient.

How do patients talk about the responsibility of other stakeholders?

In conversations with patients about the stigma related to having COPD, some patients did express concerns about the prioritization of their own disease in the field of research. A recently diagnosed patient living in the suburbs of Copenhagen expressed concerns about a lack of interest and mobilized focus on her disease. She said, 'I feel like we're being left in the lurch when it comes to research.' COPD, the third leading cause of death worldwide, has been identified as representing a major global unmet need by the World Health Organization (Fazleen and Wilkinson 2020). In academic debate, COPD has been depicted as a disease neglected by clinicians, researchers, and drug companies (Barnes 2007). Although the growing prevalence of COPD has also led to increased focus on the disease, this is disproportionate to its severity. When discussing what the responsibility should be of other stakeholders such as governments, scientists, or industry in this regard, a Danish patient responded: 'I want a political focus on developments of cures rather than just treatment for my symptoms and [advice on] changing lifestyle.' She also wanted more public debate about the overall direction and purpose of research. Interestingly, for her it was a political responsibility – that is, a governmental issue, and not something that researchers and industry were considered responsible for.

We found that patients, both in Norway and Denmark, responded to questions about the responsibility of scientists and commercial actors with references to trust in the overall process of drug discovery and development. They believed that the regulatory framework guiding the work of medical research and medical professionals was well functioning, even though they had very little concrete knowledge of this framework. One 52-year-old man living north of Bergen said,

> You know, basically, all the medicine I get has been thoroughly tested (…) well maybe not the COVID vaccine, but normally I think that it's all safe and tested, maybe because of the country I live in.

Interestingly, despite the public debate during the COVID-19 pandemic on the legitimacy of drug discovery and testing across the globe, the interviewed patients did not ascribe to any critical narrative about drug discovery. Most patients did not distinguish much between the roles of scientists and the pharmaceutical industry in the drug development process. It is as if a general feeling of trust in societal institutions also flows to the conduct of international pharmaceutical companies, patients seeing it as *one* innately good thing, doing work to help them. However, some did mention that they would dislike it if pharmaceutical companies earned a disproportionately large amount from the COPD drugs: 'You can't put a price on human health,' said one man in his late

seventies. He elaborated that the industry should be rewarded for the time and resources spent on drug development, but there should also be limits to the profit that they can make. When asked who should be responsible for this, patients tended to believe that it should both be up to the regulators and the pharmaceutical industry.

We found a striking expression of trust and readiness to delegate responsibility to 'experts.' These responses might reflect the type of informants that we were engaging with: resourceful citizens in Nordic welfare states who were willing to engage in our research, as they had previously done in clinical trials. Yet most of them were diagnosed with COPD late in their lives, and were not interested in playing an active role in setting research agendas like other patient groups have been (see e.g. Callon and Rabeharisoa 2008; Navon and Eyal 2016).

Scientist perspectives

How do scientists talk about their own responsibility?

Of all stakeholders, senior researchers knew most about the ideals embedded in policies and notions of RRI. This makes sense due to their time in the field and because they themselves had drafted the application for the grant to fund the research that included an RRI element. For junior scientists who were hired as postdoctoral researchers or PhD students, thinking in terms of an RRI framework was new. Despite different levels of engagement with the concept, and regardless of their seniority, their understanding of responsibility had to do with research integrity and the pre-existing set of rules and duties that govern the drug discovery and development processes. One senior scientist, who had been working in the field of drug discovery for decades, stated that responsibility in research was about 'following the rules, the ethical guidelines—and […] educate people [at the University] and produce research.' Echoing findings in previous research (Felt 2017 Glerup and Horst 2014;; van Hove and Wickson 2017 and Åm, Solbu, and Sørensen 2021), the scientists already considered their practices responsible and RRI was discussed more as passive compliance. It was called 'a necessary funding demand' that were not always easy to apply to their own work. This indicates that research quality is considered the main way of exercising responsibility, while the RRI framework is regarded as extra assignments, i.e. additional obligations, often tied to funding requirements, rather than integral to the core research responsibilities of scientists.

RRI frameworks in policy papers have drawn criticism in academic debates for placing the responsibility of science governance solely on scientists' research practices (Åm 2019). Additionally, there is a noted misalignment between the portrayal of scientists in policy papers and their self-representation in interviews (Åm, Solbu, and Sørensen 2021). Our interviews point in a similar direction. Scientists saw their own efforts to master scientific practices as a proxy for responsible engagement with society. Producing 'good research' was the main way to reach the overall goal of helping patients and creating gains for society. A junior scientist explained: 'As a responsible researcher I think we have to give our best to do good science […] It's just curiosity-driven research I think to do our job, but then to do it in a good way.' Doing good research also meant that patients and society in general were important for the scientists to think about; and as we will show now, scientists did have concerns about transparency.

What are scientists' preferences when it comes to engaging with other stakeholders in the research and innovation process to improve societal influence in drug discovery?

One scientist claimed that science was becoming 'a religion' due to lack of societal transparency about mundane research practices and the organization of drug discovery research. In his opinion, this lack of transparency led to research becoming a system where scientific practices were difficult for people to critically relate to in the ways that they ought to. Some of the senior scientists participated in public debates about the direction of drug discovery and production. One of them explained: 'Different relevant groups should be able to know about the basics of drug discovery because it's a question about what kind of society we want.' She was implying that knowledge equals better societies: it allows for informed conversations about resource allocation and the broader societal implications of drug development in e.g. patient advocacy groups. Most of the respondents considered that people with expertise in science communication should be left to debate the societal issues surrounding the discovery of new drugs. Scientists mentioned their lack of available time and inadequate communication skills as main factors that concerned them when thinking about doing it themselves. When it came to engaging with the patient groups that could be the potential users of the drugs they were developing, the scientists rejected the idea. A senior scientist working in the field of medical chemistry for the past decade stated:

> Patients are at the core of what we do, but we will raise false hope if we engage with them directly. There's nothing in the pipeline. The research we're doing is at such an early stage.

This scientist believed that it was too early to establish a meaningful direct connection with potential patients, while researchers were still developing the molecules. Another scientist said: 'It's more the point that we must consider the greater good in the projects.' Responsibility here was about working for a better future for patients, and avoiding routes that were not beneficial for patients and society. These patients were, due to the temporality of drug development, not considered concrete patients yet, as there was no treatment to offer.

When drug discovery projects are in their early stages, the target population for the possible drug is not entirely defined. This makes inclusion of patients a precarious endeavor while there is a chance for expansion and/or interchangeability of the target population depending on both the properties of the drug and on strategic concerns. Early drug discovery was thus not considered suitable for patient-engagement. The researchers debated with technology transfer experts and commercial representatives that instead of focusing on COPD patients as the end user of one of the new drugs being developed, it could instead – or also – be targeted to cystic fibrosis patients. While this adjustment would not significantly impact the researchers involved, it has the potential to broaden the user base for the new drug. Furthermore, considering cystic fibrosis patients as the primary research population for future clinical trials was discussed. This approach was seen as a better opportunity for marketization and industry investment in the developed molecules, given their fewer comorbidities and greater accessibility for enrollment.

How do scientists talk about the responsibility of other stakeholders?

In many ways, scientists found the current modes of organizing drug discovery research lacking in a sense of responsibility. While much of this conversation circulated around

commercialization, the concerns were rarely directed at pharmaceutical companies, but rather to the organization and regulation of academic research and commercial entanglements. The notion of 'organized irresponsibility,' developed by sociologist Ulrich Beck (1992), highlights the processes in which it is no longer possible to identify which decision-making agent bears the responsibility for harmful consequences. This notion is useful in understanding the sentiments of the scientists. Many of the scientists had concerns about the relationship between the publicly funded university research they were doing and commercialization interests of industry. Research has shown that 'corporate' and 'academic' research can in practice be entangled (Wadmann 2014). One consequence of what can be understood as organized irresponsibility is the limited possibility to conduct basic research. From the perspective of a senior researcher in the field, this entanglement placed undue responsibility on the scientists, as they had 'to focus on what big pharma does not,' in order to ensure that research was not dictated by commercial interests.

Similarly, other scientists expressed how it was difficult to achieve academic freedom to focus on research they found most interesting versus research deemed impactful by funders and pharmaceutical companies. Instead, they were led by a quest to – in the words of one scientist – 'deliver an immediate impact on society' that was 'misleading the researchers.' This researcher expressed unease with scientific work becoming increasingly focused on its capability to be commercialized: 'In this way, pharma basically dictates the direction of research.' Due to internal discussions about potential patenting, some findings within the project were kept confidential throughout the project. While commercialization is a necessary route for most new drugs to reach patients, we see here that there is also a focus on how irresponsibly organized drug discovery and development limits the opportunities to do research that might not have an immediate uptake by the pharmaceutical sector.

Another form of organized irresponsibility that was raised was the lack of transparency and support when it came to taking novel findings down a commercialization road. The development of new drugs relies on massive investment, and their production requires the expertise, skills and knowhow of individuals operating within the industry. The frustration was targeted at the way that pharmaceutical companies would show a not-entirely-genuine interest in the compounds that scientists were developing: 'I think that the pharmaceutical companies should be honest about their interests—if and when they have an interest' a scientist stated. Another part of the frustration of the scientists was about the support that could be provided by the publicly funded universities and funding agencies. Scientists suggested that, to enhance the sustainability of drug discovery and development, universities and funding agencies should have the capacity to offer comprehensive support for transferring discoveries from the academic to the industrial domain.

Scientists – at the forefront of making new discoveries – are inherently placed in the unfortunate position of having to decide whether to share and publish new findings or preserve potential intellectual property (IP) rights. In practice, it is particularly difficult for researchers to define the line between precompetitive discoveries at the basic research stage (where open access/open science is encouraged) and competitive developmental research (where the preservation of patent rights become relevant) – in order to know when they should openly share knowledge and when they should contact the technology

transfer office to discuss whether patent protection should be sought. Several scientists mentioned that it should be clearer when to publish and when to withhold findings based on a potential to patent the scientific work. As one scientist remarked: 'We never patent at the right time.' This quotation shows a frustration when it comes to defining when drug targets being developed should be patented. The project researchers decided to hold back publishing particular compounds because of the non-disclosure requirement of their laboratory, to preserve the patentability of their findings in the future. This affected the work of the doctoral and postdoctoral researchers in the project as their career development depended on publishing 'good' scientific publications rather than publishing findings that they believed contributed minimally to advancing the state of the art. 'It's a very difficult position to be in for our work and career,' explained one junior researcher. The scientists' doubts related to commercialization versus openness caused tension among some of the junior researchers who were relying on publications for career advancement.

Hence, while underscoring the importance of quality research, scientists hold significant reservations about early patient involvement and voice concerns regarding transparency, commercialization entanglements, and the intricacies of determining when to preserve patent rights. These collective challenges substantially influence their academic freedom and research focus.

Pharmaceutical industry perspectives

How does the pharmaceutical industry talk about its own responsibility?

The pharmaceutical industry plays a central role in drug development, hence implementing RRI frameworks in drug discovery and development requires the industry's involvement.

The industry representatives we interviewed, not being scientists themselves, brought diverse backgrounds to the table, primarily in business and administration. Their roles were focused on either Corporate Social Responsibility (CSR) initiatives or shaping the regulatory framework for the industry. However, representatives from the pharmaceutical industry who we engaged with had rarely even heard of RRI. Unlike the RRI focus and funding demands on the scientists working at the public universities, pharmaceutical companies do not have any formalized requirements. Scholars have reported that RRI has never gained fertile ground in commercial companies' activities (Gurzawska, Mäkinen, and Brey 2017). One consultant who had been working with marketing drugs for ten years explained:

> Responsibility is a given, we want to do a good and responsible job while thinking about getting drugs to the market. Drug innovation takes many years, and a lot of time and research goes into it before a new drug can hit the market. And of course, commercial gain is one of the main responsibilities we have.

In this quotation, the industry representative articulates 'doing good' and creating financial gain as the main responsibilities, given the time and resources spent on developing a drug. With no commercial gain, drug development would not be sustainable. Thus, thinking about financial gain is also a responsibility towards the investors and other people involved in the drug development as a whole. This

entailed that they – just as the scientists working in publicly funded universities said – do their job well: that is, they focus on developing the best possible drug and getting it launched.

When discussing the focus on the continuous alignment of 'research and innovation to the values, needs and expectations of society,' which is the most commonly agreed upon element of RRI, industry representatives stated that it 'makes sense' in terms of profit and patient needs. They readily agreed that this element had both instrumental and moral value (cf. Garst et al. 2017): 'The industry has gotten punished for having too narrow perspectives on their market […] we didn't always succeed as we imagined,' said an industry representative with 20 years' experience. However, she and all other pharmaceutical industry representatives meant that they already had responsibility institutionalized, by referring to Corporate Social Responsibility (CSR) in their organizations. One product advisor working in a multinational pharmaceutical company explained: 'We've already built it into the strategy.' This advisor spoke both of responsibility (through CSR) and working to align outcomes with the needs and expectations of society through surveys, in-house anthropologists, and public engagement. CSR is an evolving concept that reflects various views and approaches regarding corporate relationships with broader society (environment and stakeholders) (Fordham and Robinson 2018). Among the industry representatives it was thought important to manage the potential unexpected outcomes of innovation (such as pollution), but much of this was considered voluntary. They could not see the 'new element' of RRI that they were not already doing through CSR and in their drug development. In this sense, they did not distinguish between the two concepts – again, these responses show what responsibility means is modulated by the actors who interpret it in their own way relative to their own circumstances.

What are the pharmaceutical industry's preferences when it comes to engaging with other stakeholders in the research and innovation process to improve societal influence in drug discovery?

One business advisor who had worked in a variety of corporations, and now had been based in a pharmaceutical company for a few years, said: 'It would be remarkably bad for business if we were not in touch with our users.' By being 'in touch with users' he was talking about the process of collecting information about patient experience with the medicine and associated devices. A main goal for the pharmaceutical industry is that their medicine is used by the patients. If the patients did not use the medicine, the business would suffer losses after what is normally a lengthy, risky, and expensive drug development. He referred to instances where the marketability of a new drug suffered because the patients could not use it due to a narrow sampling in the clinical trials, or too little attention to side-effects. He continued: 'We want to improve the uptake of our drugs, but it takes much more to open up our production process and I'm unsure if it makes sense to do [that] before the clinical trials.' One of the reasons given for this was that it could cause issues in terms of confidentiality. To preserve the validity of a patent, including its novelty and inventiveness, confidentiality is required to meet the non-disclosure requirement before filing a patent application. However, this confidentiality comes at the expense of sharing findings related to the innovation (Clozel 2011). 'Do you mean [giving end users] direct impact on the development of

drugs? We don't offer that,' answered another advisor, who added that including patients or publicly funded researchers in the entire process was not realistic because of the competition with other pharmaceutical companies. He explained: 'We engage with society on a general level, when we are invited to public debates and other engagement activities.' This advisor had attended several public debates regarding the direction and new trends in their pharmaceutical company and industry at large. Public engagement was part of the company's strategy to create legitimacy surrounding its work.

When asked if public debates could be classified as CSR, one of the representatives replied: 'No not really. Maybe. We do have a responsibility to be "out there". In dialogue.' This answer shows doubt about what activities are classified as CSR, while there is no doubt that active participation in discussions and interactions with different communities is a crucial activity for many of the pharmaceutical representatives. Inclusion of scientists and patients during the innovation process, was, however – from the perspective of the industry representatives – unrealistic.

How does the pharmaceutical industry talk about the responsibility of other stakeholders?

When it came to responsibility to the universities and scientists who were studying new disease mechanisms, one representative stated: 'We need a lot of research in the life sciences before we have something we can call a novel finding that we can use to develop new drugs. Scientists need to be realistic about what a novel finding is, and there should be even more public investment in life science research.' Expanding the pool of basic research was the responsible way to improve the conditions for bringing new drugs to the market. The people working in the pharmaceutical industry argued for more public investment in research at universities. This is in contrast to the scientists' perspectives, who felt as if pharmaceutical companies were not always being honest about their interest in the drug molecules. This example illustrates the difficult task of operationalizing RRI when conceptions go in completely different directions.

When discussing the prospect of the RRI framework in the pharmaceutical industry, the industry stakeholders were skeptical about an unincentivized adoption of normative actions aimed to include more stakeholders, especially patients, in the drug development process. RRI has been described as difficult to achieve if perceived as something that is 'bolted on' or in some way separate from the core activity of the company (Porcari et al. 2020). However, representatives from industry truly could not imagine a company being on board with RRI policies. One informant was very much against RRI policies in the company due to his belief that the company was already doing their work in a responsible manner; but, taking stakeholder perspectives into account when relevant, another representative stated:

> If we were to implement RRI frameworks, we need to look at the regulatory side of things. Much of what we do is about aspirations but is basically determined by the rules that are being set. Regulation controls us. When I discuss with the authorities I always say, 'Make some demands and then we will follow them'.

The so-called 'political questions' of inequality in access to, or the availability of, drugs or the influence in drug development, were considered the government's political responsibility to solve through regulation. Several informants did see challenges when it

came to meeting societal needs through market mechanisms only and recognized the complexity of matters related to unavailable treatment or other problematic trends: one example is the development of antibiotics, for which there is currently no viable market (Klug et al. 2021). One representative stated that there was a need to bring solutions to society, not through market mechanisms, but through 'thinking outside the box.' What we see here is the willingness to engage in broader questions of agenda setting, societal issues and inclusion. However, it was clearly articulated as the responsibility of regulators to make demands and not the responsibility of the industry.

Discussion

Our interviews about responsibility and stakeholder engagement created a particular space for people to speak about their concerns and perspectives on certain elements of drug discovery and engagement with other stakeholders. Table 1 provides an overview of the different conceptions that patients, scientists, and industry representatives hold. In the first part of the discussion, we highlight the tensions and similarities between the different conceptions of responsibility. In the second part, we look deeper into the claim that stakeholder engagement in project trajectories strengthens so-called responsible research.

Conceptions of responsibility

The normative purpose of RRI has been to improve modes of conducting research and innovation through collective responsibility rather than delegating responsibility as an individual issue (Karner et al. 2016). However, as we see from our results, understandings of responsibility shape the conversation in many directions with people. For all stakeholders, responsibility was first linked to their own behavior and to what they already know: Patients spoke about personal responsibility by echoing or opposing discourses

Table 1. Summary of key findings.

	COPD patients	Scientists	Industry representatives
How do they talk about their own responsibility?	Responsibility is linked to their own health behavior. Some are willing to embrace 'more responsibility' while others consider it stigmatizing.	Responsibility is linked to the integrity of their own research practices.	Responsibility is linked to running a sustainable business while developing drugs and the concept of Corporate Social Responsibility (CSR).
How do they want to engage with other stakeholders?	They do not expect or desire influence on drug development. They express trust in the process of drug development.	They do not desire direct contact with patients during drug development as they are concerned about raising false hope about the availability of new medication.	They do not desire involvement in the drug development process due to potential confidentiality issues.
How do they talk about the responsibility of other stakeholders?	They have concerns about prioritization of diseases in the research and health sectors.	They are concerned about funding structures, over-emphasized quests for impact, and tensions between patenting and open science.	They are concerned about increasing the pool of available research from universities, and marketization. They expect governments to regulate and incentivize responsibility.

on certain health behavior as 'responsible.' For scientists, responsibility was primarily about research integrity. They expressed responsibility towards potential future patients. Industry stakeholders translated responsibility into an existing framework of CSR or rephrased it as commercial gain. In this way, stakeholders referred to concepts they already find relevant and highlight their own responsibility to do good either in their respective professions or as patients. Patients' understanding of responsibility as something linked to their health behavior might help to comprehend their hesitancy to engage in early drug development, as it may be perceived as a call for a specific type of accountability from their side. Both scientists and industry representatives spoke about inflexible institutional infrastructures as something that defined the maneuvering room for acting 'responsibly.' However, they had different interpretations of ways to achieve socially responsible and desirable objectives. Scientists were concerned about the direction of research due to the quest for impact and marketability, while industry representatives expressed the importance of increasing the availability of 'potential' drug innovation through even more focus on impact-driven university research.

Through interviews we also found that scientists have concerns about not being able to publish because they fear they will jeopardize the patentability of their findings. In this case, competing understandings of responsibility are at odds with one another: is it responsible to preserve IP rights or is it responsible to publish publicly funded research? While public and private foundation funding covers much of the basic drug discovery research conducted in Scandinavian countries, funding opportunities and infrastructure are limited outside the pharmaceutical industry when it comes to drug development. IP rights are fundamental to industry to ensure commercial viability in continuing to bring new drugs to market (Roy 2020). The confusion that scientists expressed in terms of sharing or withholding findings might point to a misperception that traditional IP rights can be asserted on all forms of data. This means that scientists can be paralyzed into inaction and opt for the safest option by not permitting access to data under their control to avoid liability or inadvertently giving up rights to their finding (Hulsen 2020). This can seem at odds with the broadly accepted policy mandate for data sharing, open science, and open access to support the advancement of scientific research and free exchange of knowledge (Caulfield, Harmon, and Joly 2012).

Stakeholder engagement and/as responsibility?

An academically contested topic revolves around the effectiveness of science governance policies that employ RRI frameworks (Bauer, Bogner, and Fuchs 2021; Cohen 2022; Owen, von Schomberg, and Macnaghten 2021). The debate centers on whether RRI can facilitate societal benefits or merely results in superficial stakeholder engagement aimed at fulfilling funding requirements. In practice, engagement often fails to challenge the traditional hierarchy between scientific knowledge and other forms of understanding, thereby lacking the influence needed to reshape research and innovation due to predetermined research questions and rigid institutional structures (Bajmócy and Pataki 2022; Frahm, Doezema, and Pfotenhauer 2022; Karner et al. 2016). Moreover, Frahm, Doezema, and Pfotenhauer (2022) have identified and problematized the emerging and increasingly standardized view in policy-making that presents the integration of

society as a 'fix' to problems with innovation and its contribution to global economic growth.

We have discovered that the somewhat 'fluid' nature of patient groups in drug discovery poses a challenge to the ongoing stakeholder input advocated by RRI. Since target populations undergo negotiation until late in the innovation process, involving patients in drug discovery and development becomes a matter of timing. Some of the patients we engaged with felt neglected, possibly due to the stigma associated with COPD as a self-inflicted disease. Engaging these patients at such an early stage, when the R&I process may ultimately lead to drug development and clinical trials for a different patient group, might do more harm than good by exacerbating their sense of neglect. It is essential to approach the inclusion of patients in the R&I process with careful consideration, recognizing that it can both benefit innovation and patient communities but can also yield unfavorable outcomes (Rach et al. 2020). Thus, we assert that a universal approach to inclusion is not necessarily beneficial for all research projects and may not align with the preferences of the involved people.

Based on our findings and previous research on the contexts that shape the implementation of RRI (Åm 2019; Åm, Solbu, and Sørensen 2021; Wittrock et al. 2021), we argue for emphasizing the responsibility of institutions and political contexts instead of placing the burden solely on research projects. Rather than assuming direct involvement in early drug discovery and development as the key means of achieving impact, alternative methods for public deliberation in inclusive forums (e.g. townhall meetings, surveys, online engagement) can offer opportunities for different publics to discuss political and organizational aspects of research and innovation. Notably, some of the key figures who initially championed RRI within the European Commission have recently suggested that RRI should also serve as a space for encouraging deliberation and contestation, allowing early and exploratory lay articulations of issues to engage in critical dialogue with prevailing policy and institutional representations. This approach fosters opportunities for political change (Owen, von Schomberg, and Macnaghten 2021). As an example of action taken on the political level, the current reform proposal in the EU might radically alter the incentives for pharmaceutical companies towards a so-called 'patient-centered approach' focusing on i.e. access to medicines and increased representations of patients in the approval of medicines.[1] While policy initiatives and legally enforceable frameworks can be used to safeguard some stakeholder interests and concerns, build trust and mitigate against potential wrongdoing, it is also important to acknowledge that public deliberation activities and initiatives to increase stakeholder representation in drug discovery create specific publics defined by resources and particular notions of relevance. Public deliberation activities could make sense for some projects, but it is not a comprehensive solution to the challenge of stakeholder engagement, as politics and power dynamics come into play during all participatory activities (van Oudheusden 2014). For decades, scholars in STS have advocated for the democratization of science and technology governance, granting individuals and collectives greater agency in shaping and influencing new knowledge and technological developments (Jasanoff 2003). Innovation processes inherently carry the risk of generating controversies or encountering public resistance, as seen in fields such as nanotechnology, synthetic biology, or genetically modified organisms (Frahm, Doezema, and Pfotenhauer 2022). In order to navigate these challenges a future where stakeholder engagement goes beyond superficiality is crucial.

Conclusion

With this study we have found complex challenges related to stakeholder engagement and responsibility in drug discovery and development based on the perspectives and concerns from COPD patients, scientists, and industry representatives. Patients emphasize the importance of trust and disease-prioritization, scientists prioritize research integrity and have concerns about commercialization routes, and industry representatives call for an approach that considers business interests and increased public investment in drug discovery research. We found that engaging patients directly in early-stage research may amplify feelings of neglect or stigma associated with certain diseases as the target population of the drug is not entirely defined. In this way, our interviews show that the stakeholders have concerns about political and organizational aspects of drug discovery and development. The diverse viewpoints serve as a foundation for future research and discussions aimed at fostering more thoughtful policy interventions that can incorporate social considerations, as much of the drug development is steered by commercial interests and market mechanisms. Different methods for public deliberation on organizational and political contexts rather than project-specific engagement can be a way forward to help clarify trade-offs and prioritize values and perspectives. However, there are crucial unresolved dilemmas related to hierarchical decision-making and underrepresentation of groups that requires a broad focus on power dynamics in organizational, political and societal contexts.

Note

1. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/reform-eu-pharmaceutical-legislation_en

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Data availability statement

Participants did not consent to the sharing of their data, and as such the data supporting this publication are not publicly available.

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