FRIENDS OR FOES? STAKEHOLDERS OF LARGE-SCALE LIFE-SCIENCES RESEARCH INFRASTRUCTURES

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Abstract: *Collection and storage of biomedical data has presented a problem for many years due to different regulations in storage and processing of samples. Efforts are being made to construct a harmonised biobanking infrastructure in Europe. This study analyses the prospects of engaging stakeholders in large-scale research infrastructures. The case investigated concerns BBMRI, a national biobanking and molecular analysis infrastructure. Different stakeholders may have different interests and perceptions, which presents a challenge in undertaking the construction of an infrastructure of such magnitude. This study seeks to understand the different perceived realities concerning BBMRI between different stakeholders as to generalise their insight. The study utilises ethnomethodology and experience-near hermeneutics. The study has interviewed 14 different respondents, each representing potential stakeholder organisations both in Sweden and internationally. The results have been evaluated through a DART-analysis. The final outcome shows that the respondents express a set of overarching themes spanning across the different organisations.*

Keywords *Biobanking, Biorepository, Infrastructure, Ethnomethodology, DART-Analysis, Experience-Near Hermeneutics, Stakeholders, BBMRI, EU.*

INTRODUCTION

Biobanks play a pivotal role in advancing public health through the discovery of diseases. Notwithstanding, a pressing problem in this day and age is the fact that diseases affect people with little regard to national boarders or citizenship. The advancement of information technology has made collaboration between biobanks more accessible but still today many challenges remain. One of the most prominent challenges is the lack of a universal standard that biobanks can adhere to, which invariably results in degradation of biosamples as they are transferred from place to place with different storage solutions. Accessibility is also a problem as many biobanks are not involved in any large scale collaboration or exchange with any other actor. This situation has prompted calls for a harmonisation of biobanks so that they may adopt common goals, principles and technology, to allow for a seamless collaboration and exchange of tissue samples (Harris *et al.*, 2012).

A current EU-initiative seeks to establish harmonised biobanks across the European Union through a new legal entity called ERIC (European Research Infrastructure Consortium). One of the instigating forces behind realising this entity is BBMRI (Biobanking and Biomolecular Resources Research Infrastructure), currently headquartered at Karolinska Institutet (Stockholm, Sweden). Over the past three years BBMRI has grown into a 53-member consortium with more than 280 associated organisations (largely biobanks) from 33 countries, making it one of the largest research infrastructures in Europe (BBMRI, 2010, para. 7).

In order for an organisation to develop a strong rapport with its stakeholders, it must successfully formulate and convey a vision that speaks to the stakeholder. In order to do this, the organisation must know the goals, desires and reasoning of the stakeholders, which prerequisites an understanding of how they feel the way they do. Hence, it is pertinent to investigate the attitudes of the stakeholders – what their views are and how they may differ from one another in light of the harmonisation efforts.

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This study places emphasis on the individual perspective amongst the stakeholders in order to determine if there is a discernible trend or common pattern in the way they perceive their reality. Ultimately, this study endeavours to discern if it is possible to develop new approaches in order to reach out to the stakeholders and address the concerns they may have on the initiative brought forward by a large-scale life-science infrastructure such as BBMRI.

BACKGROUND STUDIES

There is a pressing need for the medical research industry to establish a new relationship between professionals, notably the medical profession and other potential stakeholders (Walshe & Rundall, 2001; Scott, Ruef, Mendel & Caronna, 2000; Hunter, 1996). Thus, one might ask how the medical management of a large-scale infrastructure should go about building a fruitful relationship with its potential stakeholders. As Van De Ven (1999) implies, it is essential for new projects to be able to develop by not only correcting past mistakes, but also by learning from them and drawing knowledge for future reference. Indubitably, this presupposes that there is a functioning means of communication with one's counterpart as only then can potential problem be addressed in a due and proper manner. Moreover, this is also in line with the rational system perspective, which emphasises the collectively oriented pursuit of relatively specific goals (Jaffee, 2001). Stakeholders are herein defined as those entities that have a potential interest or gain in the infrastructure. Freeman (1984) defines this theory as an attempt to address the "principle of who or what really counts" (p. 46; Mitchell, Agle & Wood, 1997). Stakeholder theory seeks to integrate the resource-based view with the market-based view on a socio-political level. Specifically, it seeks to define who the stakeholders are, and under what conditions they can be considered "stakeholders" (Donaldson & Preston, 1995). Indubitably, the stakeholder will have an agenda of their own and different conception of reality as they perceive it. Consequently, it is of the utmost importance to attempt to discern if there is a common denominator, or argument, that signifies a majority of the stakeholders, or if each perception of reality is case specific to each individual respondent. Vogel (2005) and Finn & Wright (2011) discusses that the three most important types of stakeholders are the ones represented by: Policy-makers, Academia and the Industry. He defines them as follows:

Policy-makers: This group involves representatives from different levels of governmental organisations. It is an important stakeholder as it provides a secure and stable source of financing as well as being able to influence new laws and regulations.

Academia: This group involves universities and other research institutes. They are important stakeholders because they can provide experience and expertise as well as a neutral environment that can unify a broad spectrum of actors. This group is also able to undertake endeavours that would be deemed too risky for commercial business.

Industry: This group involves (chiefly private) biotechnological and pharmaceutical companies. This group is the engine that provides capital, revenue and viability for the enterprise.

METHODOLOGY

The field work for this study was carried out in the autumn of 2011. The aim of this study is to examine and analyse the holistic aspects the potential stakeholders in the biobanking harmonisation initiative, spearheaded by BBMRI. The empirical data was documented through audio recording in order to ensure full verbal accuracy. The respondents were selected through *purposive sampling* (Oliver, 2006; Silverman, 2010). This means they have been selected from a set of different criteria relating to the aim of this study. Specifically, this entails that they represent an organisation that has a potential interest in a harmonised biobank infrastructure, and can thus be deemed a potential stakeholder in addition to associating in the same community as BBMRI. To the greatest extent possible, this study has availed itself to make use of the official designations and translations for names, titles and concepts etc. as provided by the respondents and their respective organisation. Where applicable, the author has made all other pertinent translations.

The approach of this study has been ethnomethodology, which tends to focus on the relationships between social action and group

members' accounts of such actions, and how those relationships are produced and managed (Garfinkel, 1967; Babbie, 2010). Ethnomethodology applies no obligatory set of methods or theory. This entails that any research procedure may be used, provided it is appropriate to the particular phenomena under study (Lynch, 1996; Feyerabend, 1993; Kuhn, 1996). While ethnomethodology may take on many different forms, such as conversation analysis, this study will look at the practical actions and practical reasoning by the respondents as this is the type most closely associated with the original ethnomethodological studies (Psathas, 1995; Garfinkel, 1967).

As the aim of this study is to investigate how the respondents view the harmonisation initiative of biobanks from their own position/situation. The hermeneutic approach best suited for this endeavour is the Trankellian experience-near perspective (Gustavsson, 2007; Gustavsson, 2000; Palmer, 1967). This perspective stipulates that any conclusions should be viewed in light of the respondents' own perspective and their own circumstances. Thus one should not attempt to infer the results on a universal scale. Furthermore, unlike many other forms of hermeneutics, it also seeks to explain phenomenon rather than just understand them. The experience-near perspective is used to establish what something *is* or *how something has happened* according to the respondent's own point of view. In a similar fashion to a witness's testimony, it takes its premise from how an individual/actor describes a certain event/phenomenon. For instance, a witness can testify that he/she has seen something, rather than how he/she feels about what has occurred. In this event, a witness seeks to shed some light on what has happened. This, in turn, is what signifies the experience-near perspective, as it seeks to observe ongoing processes in order to better understand the individual behaviour (Burrell & Morgan, 1979). However, it is important to remember that it is merely the witness's/respondent's own observations and perceptions that are in question, and that there may be other factors that measure into the equation of what lies behind the true story. That is not to say that the respondent's accounts do not portray a true depiction of reality. Rather, it is a true depiction of reality as he/she sees it. On a general level, there is little that differentiates the investigative procedure of the experience-near hermeneutics from that of the more traditional type of hermeneutics, also known as the *experience-distant* perspective (Gadamer, 1975). However, one fundamental element that separates the experience-near perspective from the experience-distant perspective is the fact that the experience-near perspective is not bound by the same constraints of the hermeneutic circle. In a practical sense, this means that the researcher shifts focus between the part and the whole of a given phenomenon during the course of research. The researcher continuously moves inside and outside of the given material so as to critically test the respondents' interpretations against the theoretical framework and criteria. The goal is ultimately to see whether or not a distinctive pattern can be discerned from the responses provided. That is to say, experience-near hermeneutics allows the researcher to understand and interpret various phenomena within the context in which they exist and/or occur. On this account, it contends that it is impossible for any concept to have an ultimate and unequivocal meaning (Waever, 1996).

Developed by Prahalad & Ramaswamy (2004), the DART-model is used to assess the responses provided by the respondents. DART is an acronym for *Dialogue*, *Access*, *Risk Assessment* and *Transparency*. The model seeks to examine the respondents' view on four important stakeholder cornerstones, and if necessary, how these areas may be improved.

Dialogue: A continuous and mutual dialogue between the actors is necessary. Dialogue is vital in creating knowledge and understanding among both parties, but it also prerequisites interest and receptiveness in order for it to be fruitful.

Access: In order for there to be an understanding for the infrastructure and its worth, there must be affluent and accessible information surrounding the infrastructure. Information tends to be asymmetrical (i.e. one party being privy to more information than the other).

Risk Assessment

All of the potentially important drawbacks and risks associated with the infrastructure must be known to all affected parties. This will allow the parties to

make well-formulated opinions where all aspects are taken under advisement so that a foundation for making fair and rational decision is present. In achieving this, an open dialogue is preferable as it may help instil confidence by discussing the risks openly rather than suppressing them.

Transparency

The level of transparency of the infrastructure affects the insight researchers and outsiders have into the project and how its operations are run. If all concerned parties are accustomed to the details and intricacies of how the projects work, the likelihood for garnering trust among the parties is higher. A higher level of transparency may also help increase the empathy and understanding for some of the operative decisions and endeavours that the infrastructure may intend to take in the future.

The Inquiries

The interview questions were constructed in a semi-structured manner in order to allow for greater flexibility for each respondent response while at the same time maintaining stringency in the study's overarching topic. Each respondent has been asked to reflect, from his or her own point of view, on the following three semi-structured questions:

- What, in your opinion, is the greatest value of harmonising Biobanking?

- What are the greatest challenges of harmonising Biobanking?

- In your opinion, what role can you see for your organisation in a large-scale life-science infrastructure such as the BBMRI?

Sample and Data Collection

In all, 13 stakeholder respondents have been interviewed. Although 14 individuals were interviewed, two of the respondents represented the same stakeholder and were interviewed jointly as one stakeholder. The respondents represented the organisations that recurrently frequented the same exhibitions and conventions as BBMRI and can thus be said to be active in the same circles. Hence, the selection is representative of the sample it reflects. This study will utilise Holmes's (2012) stakeholder model in discerning which of the stakeholders are "friends" of harmonisation and BBMRI and which of the stakeholders are "foes". This stakeholder model also tries to elucidate the potential impact each stakeholder might have on the enterprise, and what actions to take and when to take them. The respondents represent a stratified sample of the three most important types of stakeholders, as previously discussed by Vogel (2005) and Finn & Wright (2011). As there are a greater number of stakeholders from the industry by and large, more respondents from that category have been selected for this study.

George - Works as a Professor at a regional hospital in the south of Sweden and collaborates with a major university in the same region. George represents an academia stakeholder.

Eli - Is the president of an influential regulatory governmental organisation with a vested interest in biobanking. Stationed in Stockholm, Sweden. Eli represents a policy-making stakeholder.

Fred - Works as a Clinical Supply Manager at a small biotechnological company in the south of Sweden. Fred represents an industry stakeholder.

Dorothy - Works as a Director of Development at the same company as Fred. Her responses are presented jointly with Fred. Dorothy represents an industry stakeholder..

Ian - Works as a Principal Scientist, Clinical R&D, at a large international pharmaceutical company. Stationed in the south of Sweden. Ian represents an industry stakeholder.

Sophie - Works as a Clinical Research Associate at an international Contract Research Organisation (C.R.O.). Stationed on the East coast of Sweden. Sophie represents an industry stakeholder.

Annie - Works as a Web Sample Administrator, R&D, at a large international pharmaceutical company. Stationed on the East coast of Sweden. Annie represents an represents an industry stakeholder.

Helen - Works as a consultant at a consultancy/ contract research organisation. Stationed on the East coast of Sweden. Helen represents an industry stakeholder.

Nina - Works as a Public Relations and Business Development Manager for a non-profit organisation that mobilises a European network of

scientific centres with experience in virology. Stationed in the south of France. Nina represents an industry stakeholder.

Daniel - Works as a Business Development Manager for the North America region at a cryopreservation biobank for biological samples. Stationed in Minnesota, United States. Daniel represents an industry stakeholder.

Keith - Works as a Business Development Manager at a provider for specialised biological material management services. Stationed in the South of France. Keith represents an industry stakeholder.

Nicolette - Works as a Regional Marketing Manager at a provider of sample and assay technologies. Stationed in the South of England. Nicolette represents an industry stakeholder.

John - Works as a scientist at a federal environment agency. Stationed in Germany. John represents a policy-making stakeholder.

EMPIRICAL FINDINGS AND ANALYSIS

Stakeholders

A DART-analysis yields the following results:

"George"

Dialogue

"George" contended that that his organisation maintained a steady dialogue with BBMRI. He took exception to the usage of the word "biobanking", saying: "What they refer to as 'biobanking' these days actually went by other names in the past, such as 'processing of bioinformatics studies' etc." At the same time he did not consider terminology to be one of the main sources of disputes. As such, there are some indications that "George" appears to lack the interest and receptiveness that is needed in order for the dialogue to function at an optimal level.

Access

"George" took the position that the agenda is being set on a higher lever and that there were "greater powers" controlling proposed direction of biobanking. He also noted the disparity of resources between his organisation and that of an organisation such as Karolinska Institutet, saying "My interests are veered towards the patients; we are not academics like the folks over at KI [Karolinska Institutet]". "George" contended that he saw BBMRI as "inaccessible" and asymmetric in terms of information sharing.

Risk Assessment

"George" emphasised the disparity of goals between his organisation and Karolinska Institutet. He clearly distanced himself from what he viewed as academic dogma in favour of taking an exclusive "patient perspective". Thus, he would see it as a risk of having to surrender his organisation's ideals to that of bureaucracy. He also appeared to favour the notion that the harmonisation efforts was a "rush job" that latched on to a current trend permeating the health sector. He cautioned against the fact that so much money was presently being invested in an infrastructure of which the ramifications were still unknown. Hence, "George" saw commitment to the BBMRI as a risk with unclear benefits to his organisation.

Transparency

"George" expressed his scepticism against the multitude of actors involved in bringing the harmonisation efforts to realisation, saying: "too many Cooks spoiling the broth!". He indicated that this impedes the overview of the project and makes it less perspicuous. This is particularly important as he also stressed the importance of upholding regular and continuous activities in order for it to be successful but it would prove problematic if such activities are not immediately known, or visible to outsiders. Hence, it is important to establish a semblance of who does what in a project. On this account, "George" perceived a lack of transparency in BBMRI.

"Eli"

Dialogue

As an instrumental organisation in the harmonisation efforts, "Eli's" organisation is ever so involved in the discussions. However, "Eli" argued that dialogue is a problem, because of different conceptions of terminology among

different actors. He also stressed the need of co-ordinating the organisation so that everyone speaks the same language. Thus, in "Eli's" view, dialogue was currently somewhat of a problematic area for BBMRI.

Access

"Eli" considered his organisation to be very influential, and has consequently got great insight in the workings of BBMRI and the harmonisation efforts. The level of access is thus viewed favourably.

Risk Assessment

The lack of a viable means of communication also leads to greater information asymmetry. Because of the complexity, the parties concerned will seldom be given an opportunity to make well-formulated opinions about the harmonised infrastructure. He also notes that the present "opt-in" legislation increases bureaucracy, which also makes information sharing more inaccessible. However, he notes that with a new legislation, the risk assessment should improve, which he exemplified by saying: "In part we can see to it that we co-ordinate ourselves to ensure that everyone speaks the same language. We are currently working on finding ways of creating a common conception and infrastructure surrounding biobanking so that we don't end up building two parallel systems we cannot use."

Transparency

"Eli's" organisation represents one of the driving forces behind the harmonisation initiative, which means he enjoys a high level of perceived level of transparency in terms of what the harmonisation work entails. He contended that his organisation's role was actually larger than BBMRI in regards to bringing the harmonisation to pass. This was because BBMRI is mainly concentrated at the academic institutions, while his organisation covers the entire biobanking array as a concept.

"Fred" & "Dorothy"

Dialogue

"Dorothy" contended that she preferred the term "tissue bank" rather than "biobank", which indicates a semantic difference in interpretation. However, the organisation did not seem to engage itself in any form of dialogue regarding the harmonisation. "Dorothy" asserted that her organisation's strategy was to wait for the new harmonisation to develop and spread as she said: "We will wait and see… what use will it bring us? We're not making any money [off it] so we are more concerned about our survival. At least, that's the honest version".

Access

"Fred" & "Dorothy" argued that joining a harmonised infrastructure would have very little effect on their company's daily routines. In fact, the only notable difference would be how the samples were registered, which "Fred" exemplified by saying: "As far as we are concerned it does not mean anything. It just means we register the samples in another way." Thus, accessibility was not viewed as a problem.

Risk Assessment

"Fred" admitted that he felt inexperienced and that he has merely upheld the routines instigated by his predecessor: "This title was passed down to me by someone who retired without really knowing what it entailed, and I still don't know what it means! I have just inherited all the routines". As "Fred" explicitly stated that he was not attuned to the businesses of a biobank, he was not able to discuss the risks associated with the harmonisation in a well-formulated manner. "Dorothy" on the other hand, expressed that her chief interest is to ensure the company's survival, while lamenting the fact that the company was not generating any revenue.

Transparency

"Dorothy" asserts that the process in a harmonised infrastructure will become more automated and mechanical. "Fred", on the other hand, said: "The thing with biobank samples is how one disidentifies the data". This suggests that there is a greater need for transparency into how the routines would function in a harmonised system.

"Ian"

Dialogue

In "Ian's" view, there did not seem to be much dialogue between his organisation and BBMRI.

Instead, "Ian" suggested that his organisation had adopted a "wait-and-see" strategy and that future dialogue was contingent on if whether or not membership would prove profitable. He meant that his organisation's involvement in the harmonisation depended on what they could "get out of it".

Access

"Ian" tended to support the current system of information management, which aims to seek approval from the company's own executives before sharing it with other organisations. This was exemplified by his statement that: "across Europe, our managing directors have to review all the cases and make the necessary arrangements so that one can find what one is looking for, and that's the way it works." "Ian" consequently favoured information asymmetry and was opposed to sharing information freely.

Risk Assessment

There were some risk factors present that made "Ian" hesitate. Specifically, "Ian" found many sources of uncertainty in a harmonised infrastructure. Most prominently he expressed concerns that his company's own samples would be processed in a much slower manner than today. He also expressed uncertainty regarding the issue of ownership of each sample by saying: "Who owns the samples? What can you do with the data?".

Transparency

"Ian" expressed concerns regarding the legal aspects and that the harmonisation was slow and unwieldy. Thus, he did not feel that he had due and proper insight to the routines of BBMRI and the harmonisation progress.

"Sophie"

Dialogue

"Sophie" suggested that dialogue was not sought as the harmonisation has no real impact on her organisation, as she said: "we only act as intermediaries between the pharmaceutical companies and the different clinics". Nevertheless, she expressed an interest in the concept, which provides a starting point for opening up means of future communication.

Access

"Sophie" argued that the harmonisation mainly concerns the "academic sphere" and thus would be of lesser relevance to her organisation.

Risk Assessment

As "Sophie" contended that here organisation merely acted as intermediaries, risks to the organisation are perceived as non-existent. Consequently, she had no desire to look into the presence of any other risks associated with involvement with BBMRI.

Transparency

The issue concerning transparency was a problem, but that could mostly be attributed to the fact that BBMRI was seen as being less relevant to "Sophie's" organisation. She contended that the image BBMRI had conveyed till this point had not given the impression of wanting to activate any other organisations except those found in the academic sphere.

"Annie"

Dialogue

"Annie" expressed that there was some dialogue proceeding between her company and BBMRI, even though she was personally opposed to it, as she argued that: "There are no benefits whatsoever in harmonising human biobank samples". That is to say that although there was a dialogue was present; it was bereft of interest and receptiveness.

Access

"Annie" understood the fundamental workings of BBMRI and the harmonisation efforts, and saw no problems concerning accessibility. On the other hand, she saw no future exchange between her organisation and BBMRI, as she said that she saw no role for her company in participating in the harmonisation efforts.

Risk Assessment

"Annie" expressed aversion to harmonisation by saying "I think it is better to distinguish, that is my opinion". That is to say that she believed it was better to hedge the biobanks as to not store them all under one roof.

Transparency

"Annie" not only rejected the entire notion of her organisation participating in the harmonisation infrastructure, but she was also inherently opposed to it as a concept, as she believed that all the important decisions were being made elsewhere

"Helen"

Dialogue

As consultants, "Helen" clarified that her organisation had no direct contact with BBMRI other than in the strictest indirect sense through their clients. She explained: "Essentially, we are consultants, so we help our companies manage [their business] but we do not run any operations like that by our own accord, rather we help others"

Access

"Helen" contended that her organisation does not deal in any laboratory work on their own account, but rather assists others who do. She expounded: "[We have] customers who request help in setting up clinical tests on patients. Nothing to do with labs per se, but rather a lot of collaborations with doctors". On this account, she claimed that the greatest impediment to full accessibility were the complicated legislative texts which led to asymmetric information.

Risk Assessment

Bureaucracy and an unwieldy legal framework are cited as the greatest adversaries to "Helen's" organisation. She argued that the present system is suboptimal as it causes unnecessary delays. She suggested that: "If one does change the legal framework, things would run much smoother. This would especially be the case with the random samples that one would collect and then register directly. You wouldn't have to await approval before requesting them like you have to nowadays".

Transparency

"Helen contends that the present legal framework hinders much of the transparency in the sense that it creates too much bureaucracy which muddles insight to the operations and routines. "Helen" expanded on this notion by saying: "The advanced legislative texts. They are too complicated and they are not quite adapted to the political trials that the biobanks are facing today. The test samples are subject to much administrative toil".

"Nina"

Dialogue

"Nina" explained that her company was presently not directly involved in the human tissue biobanks but rather with animal samples. She claimed that: "The problem with BBMRI is that it is only for humans and we are virologists [who are] interested in mammals" Consequently, her organisation is not currently discussing the harmonisation initiative. Nevertheless, she was personally in favour of such developments as she opined: "I don't see how that could be bad".

Access

"Nina" believed accessibility to be crucial, as she stressed the importance of having the same routines and regulations among biobanks, saying: "It provides possibilities of getting the same quality of samples irrespective of where they have been collected". Currently, accessibility was a problem, but she hoped that harmonisation among human-tissue banks would bring about a change in the future also for the animal-oriented biobanks.

Risk Assessment

The greatest drawback with BBMRI (and the current movement towards biobank harmonisation) was deemed to be its sole focus on human tissue samples, saying: "At the moment, BBMRI is completely different [to what we are doing]. The only thing that is useful [to us] are their efforts of harmonising the biobanks". Thus, in "Nina's" view, collaboration from her organisation does not seem likely for the foreseeable future.

Transparency

"Nina" conveyed that the transparency of the harmonisation is perceived as satisfactory, saying: "I think it [harmonisation] is a good thing, because it gives you an opportunity to share [samples] and it cuts bureaucracy". "Nina hoped that the transparency would lead to harmonisation to spread to the non-human tissue biobanks as well.

"Daniel"

Dialogue

"Daniel" contended that there is no dialogue with BBMRI, in part due to the fact that BBMRI is an EU-project, and in part because biobank harmonisation in the United States is still very premature. He accentuated this notion by saying: "The U.S. is very different from Europe. Europe is light years ahead of the U.S.".

Access

"Daniel" found accessibility to be a major cause of concern as much of the research conducted by companies are withheld from other scientists and organisation due to the manner in which these institutes are funded. He explained: "In the US, [harmonisation] is very difficult, because of the way they [the biobanks] are funded and they keep their research to themselves". Needless to say, this creates information asymmetry, which "Daniel" argued was worsened by the fact that the idea of harmonisation lacks promotion in the U.S. To this point, "Daniel" lamented: "Nobody in the U.S. is promoting that idea! Money! Money from all angles! It costs too much to get all the legal stuff done!". "Daniel" called for the U.S federal government to exercise better regulations in this matter.

Risk Assessment

"Daniel" asserted that one of the greatest risks with the harmonisation initiative is that one might involve actors who are not devoted to their work and instead look for ways to cut corners, which ultimately risks jeopardising the entire enterprise. As "Daniel" asserted: "you have to have passion for it". He also contended that another risk is getting key actors involved due to the overall scepticism in the U.S. towards transferring control over research findings to centralised institutions.

Transparency

"Daniel" argued that transparency today is suboptimal as the biobanking standards in the U.S. are extremely divergent. As a means of remedy, "Daniel" suggested: "I wish they would harmonise Europe and use the U.S. as a guinea pig". "Daniel's" main objection was that the current situation in the U.S. prevents each actor from getting insight and understanding of the other actors' methods and standards. This, in turn, could potentially present an obstacle in the event that a harmonisation of the biobanks comes to pass.

"Keith"

Dialogue

"Kevin" replied that no dialogue is presently being held in his organisation regarding harmonisation of biobanks. He contended that there were too many barriers that had to be overcome before it would be viable, arguing: "The harmonisation of biobanks sounds like an ideal, a bit like the European Union. Great in theory but a lot of things need to happen… It took the European Union forty years, that's the state they're [BBMRI] in here".

Access

"Keith" saw accessibility as a problem, because researchers will want to exercise some level of control over their own samples and they will not want to relinquish their work without being involved in what happens to it, or without receiving due credit for the work they have done.

Risk Assessment

"Keith" emphasised that one of the greatest risks was the lack of coherence and regulatory structure. He maintained that the lack of such regulation is what has enabled there to be so many different biobanks on the market, some more serious than others and that there ought to be fewer and better regulated biobanks on the market. He expanded on this point by stating: "Every university or whatever with cold [storage solutions] can in fact call it a biobank. I hope they will change it. These small ones springing up all over the place… Sort of counterproductive really. It's better to have three more monitored and controlled biobanks".

Transparency

"Keith" opined that there is a lack of transparency because there are too many active actors on the market. The suggestion "Keith" presented to remedy this is for the national governments to take more control and establish stricter regulations on biobanks by saying: "The national governments

should take the lead in securing the ongoing development of the harmonisation".

"Nicolette"

Dialogue

Although her organisation was not currently actively discussing the implantation of harmonisation, "Nicolette" asserted that she was still very interested in the discussion. She posited that: "Harmonisation is key", as without it, there would be severe tax dollar issues. That is to say that with a harmonised infrastructure, money would not be seen as indiscriminately wasted in the event that the researchers undertake studies that are later deemed to have failed.

Access

"Nicolette" argued that accessibility might present a problem in the event that all connected biobanks are forced to change storage solutions. The result would be that a risk of the development running idle and effectively award monopoly to certain storage manufacturers.

Risk Assessment

"Nicolette" contended that one of the greatest risk factors in harmonisation is that there will always be free agents who care less about ethics and more about profit. A harmonised infrastructure will not be able to remedy this problem, as she hypothesised: "If I want to research a disease and I had a bazillion dollars, I would set up my own repository, I'd find the dirt poorest country in the world, I'd hand out thousands of dollars in cash to participants to harvest what I need, and you could combine it to whatever you want". Thus, "Nicolette" argued that it would not be necessary for everyone to join a harmonised biobank infrastructure, should one ever come to pass.

Transparency

"Nicolette" contended that transparency is bolstered by the fact that there are academic institutions in charge of the harmonisation initiative. She argued: "If the biobank could be in an academic centre, they would be readily available, wouldn't they? You have a scientific guideline. So you wouldn't just give them to anybody". She argued that this ensured that ownership and intellectual property claims would not present an obstacle for the samples found in the harmonised biobanks' collections. Instead, she envisioned that commercial actors would make their samples available to all public funded researchers and prompt other private actors pay for the samples.

"John"

Dialogue

As "John's" organisation deals in animal samples, the proposed harmonised infrastructure for human tissues did not directly concern him. Nevertheless, "John" was positive towards the concept of harmonisation and hoped to see a similar development also among the animal biobanks. He also added that he regularly talked to different actors about the harmonisation of biobanks and that this was a recurring issue.

Access

"John" argued that should harmonisation spread to the animal biobanks, it may adversely affect the accessibility for some specialised biobanks that research rare and uncommon diseases. He hypothesised: "Some animal biobanks would have to give up their specialty. Especially those biobanks that are very specialised in a narrower subjects and diseases. They would have to give their specialty in favour of the 'golden standards', that is mainstream samples and research". The contention was that the cost of harmonisation would be too high for that category of biobanks to run parallel systems and they would have to conform to the majority standards at the expense of their speciality.

Risk Assessment

"John" cited cost as the most prominent risk with harmonisation. Some of the smaller biobanks simply cannot afford to switch out their storage solutions to match the new harmonised standards, which may result in a dearth of small-scale biobanks. However, on a personal level, "John" said he was in favour of harmonisation, as he added: "One must follow the development and see the benefits. On the whole, it helps more than it hinders".

Transparency

"John" believed the he had a good understanding of how the harmonisation work was intended to develop. Thus, he thought of the process as being transparent.

"Mike"

Dialogue

"Mike" said that his institute was not currently involved in any ongoing dialogue in regards to harmonise the biobanks and the interest to do so was modest at best. In fact, "Mike" explicitly stated that he did not believe that the harmonisation of the biobank infrastructure was unequivocally good. More specifically, he took exception to the concept of harmonising the biobanks to one universal standard as he contended: "Some limited harmonisation could be good, but perhaps done so that five or six different institutes operate with different standards so that they can research in their own direction". The main argument behind this reasoning was that if there would be only one universal standard that all biobanks would adhere to, it would stymie the research in the event that the elected standard would prove suboptimal

Access

"Mike" added that access to information is becoming a lesser problem as costs of sequencing has dropped exponentially in the past few years. He also favoured openness over integrity in order to ensure accessibility, saying: "We should not get hung up too much on trying to protect privacy because it will, ultimately, not be entirely possible to ensure that this can be done on all levels". He added that he had full confidence in the existing laws that would be able to deal with any transgressions of this nature in a due and proper manner. To this point, "Mike" emphasised the need of having an "opt-out" model, in which patients have the possibility to have their samples withdrawn from the biobanks, as the patients need to feel that they are in control over their own samples.

Risk Assessment

One of the greatest difficulties is setting up a system that can handle the streams of data. He lamented that: "We can sequence your whole genome, but we don't know what to report back". He reasoned that expenditure was a lesser concern, as "the cost of sequencing has dropped faster than the price of computers". Instead, "Mike" argued that for those biobanks who wish to harmonise their systems, the main problem is finding an agreement on how to handle information rather than finding a way to implement the harmonisation procedure.

Transparency

"Mike" thought the biobank procedures in the future would be quite transparent, citing laws and regulatory framework that will help bring this to pass.

RESULTS

The first table indicates the stakeholder(s) in question. The second column shows what category of stakeholder the respondent represents. The third column reveals if that stakeholder can be deemed a "friend" or "foe" to the harmonisation of biobanks. The fourth column provides succinct motivations, based on the data elaborated upon in the DART-analysis. The fifth column designates if the respondent is positive, neutral or negative towards harmonisation and what it sets out to achieve. The sixth column succinctly brings up some recommendations of the main courses of action that could be taken in order to better address each respondent's concern.

CONCLUSIONS

This paper has analysed the responses from 13 different potential biobanking stakeholders representing different organisations, and how they perceive the pending harmonisation of biobanks. Their responses were analysed according to Prahalad & Ramaswamy's DART-model and the results yielded that in terms of dialogue, five of the respondents were interested in harmonisation as a concept but were not discussing the matter within their own organisation. Three of the respondents were already actively discussing harmonisation within their organisations, although one ("Annie") admitted to doing so reluctantly. Three respondents cited that they were not discussing harmonisation due to the fact that it was not deemed interesting enough as a concept for their organisations. Two

Table 1
Friend or Foe? Stakeholder Analysis

Stakeholder	*Represents what Category of Stakeholder?*	*Friend or Foe?*	*Reasons for Being A Friend or Foe?*	*Their Perspective or View Towards Harmonisation and what It Sets out to Achieve (Positive/Negative/Neutral)*	*Action Needed to Be Taken and at what Stage? (Start, Middle, End, Throughout)*
George	Academia	Foe	Believes harmonisation does not engage concerned parties	Negative	Engage other actors on different levels. Start
Eli	Policy-maker	Friend	A leading force in harmonisation	Positive	Maintain good rapport. Throughout
Fred & Dorothy	Industry	Friend	Open to the possibility of future collaboration	Neutral	Emphasise success of enterprise. Middle
Ian	Industry	Foe	Favours ownership of samples	Negative	Highlight advantages of sharing knowledge. Throughout
Sophie	Industry	Foe	Sees harmonisation as too "academic"	Positive	Reach out to a wider audience, such as the industry. Throughout
Annie	Industry	Foe	Believes in disparity and in hedging samples	Negative	Highlight the advantages of centralised storage. Start
Helen	Industry	Friend	Favours harmonisation if understood better	Positive	Work towards making the judicial framework more intelligible. Throughout
Nina	Industry	Friend	Favours harmonisation also for non-human tissues	Positive	Reach out to non-human biobanks. End
Daniel	Industry	Friend	Hopes the U.S. will follow	Positive	Increase awareness in the U.S. Middle
Keith	Industry	Foe	Believes it is unrealistic	Neutral	Discuss prospects of success. Start
Nicolette	Industry	Friend	Sees pros and cons but agrees it is important	Neutral	Emphasise what makes joining harmonisation unique. Throughout
John	Policy-maker	Friend	Favours harmonisation also for non-human tissues	Positive	Reach out to non-human biobanks. End
Mike	Academia	Foe	Believes only in limited harmonisation	Negative	Increase awareness in the U.S. Middle

Based on table 1, the following table illustrates a compilation of the results according to respondent category:

Table 2
Friend or Foe? Category Results

Stakeholder Category	*Total*	*Friend*	*Foe*
Policy-makers	2	2	0
Academia	2	0	2
Industry	9	5	4

respondents adopted a "wait-and-see" strategy, pending the development of the harmonisation. Two of the respondents added that they thought of the terminology used as being too complex.

In terms of access, most respondents (five) found accessibility to be a problem for various reasons. One of these respondents ("George") argued that the agenda was being set on a higher level without the individual actors being able to exercise any influence. Three respondents argued

that accessibility was not a problem, whereas one respondent ("Sophie") maintained that the question was of no consequence as it was happening in a different sphere. Two respondents believed that accessibility not to be a problem today, but argued that it might be in the future under certain conditions.

When it comes to risk assessment, the responses tended to be quite disperse. However, three respondents argued that overwhelming bureaucracy would present a risk for those wanting to get involved. Two respondents expressed uncertainty about what their organisation could benefit from joining. Two other respondents expressed fears of frivolous actors joining in the harmonised infrastructure. One respondent ("Helen") thought unwieldy routines presented the greatest impediment. Another respondent ("Annie") saw a risk in storing all the samples at one location and thought it was best to spread them around at different places instead. Yet another respondent ("John") thought that it would be too expensive for some biobanks to join, whereas another respondent ("Keith") cited the lack of regulatory structure as a risk, as there could be no coherence without one. One respondent ("Sophie") thought of the issue as irrelevant as they would not join in such an endeavour anyway, whereas one other respondent ("Nina") lamented the fact that the current initiative only pertains to human samples, which is seen as a missed opportunity from engaging the non-human sample biobanks.

When reviewing transparency, four respondents believed there was already a good sense of transparency in harmonisation efforts. Four more thought that transparency was being hindered due to the lack of insight of various routines caused by too much cumbersome judicial bureaucracy. Two of the respondents thought that transparency was muddled by the fact that the decision-making was being made by other actors and excluded the ones affected by it. One respondent ("Sophie") thought that the harmonisation only caters to the academic sphere and therefore rendered itself irrelevant. One other respondent ("Helen") believed that there were certain problems with transparency now due to complicated legal frameworks, but that the problem would disappear in the future as new frameworks were established. Finally, one respondent ("Fred" & "Dorothy") thought of transparency as being weakened by uncertainty as to how the technical routines would be handled and how the issue regarding disidentification of data would be processed.

Like many ethnomethodological studies, the framework assumes the possibility of several different variations of the outcomes depending on each individual response. Nevertheless, the results above indicate that seven of the respondents can be considered friends of the harmonisation infrastructure. This implies that they are prepared to support the current biobank harmonisation, either practically or morally. Conversely, six respondents can be regarded as foes, as they tend to oppose harmonisation as a concept for various reasons. Most commonly, these reasons related to ownership issues, management structures, perceived alienation etc. Curiously, two of the "foes" ("Sophie" & "Keith") mark an exception to this rule as they did not hold explicitly negative views towards harmonisation as a concept. In these cases the respondents were sceptical towards harmonisation because the current endeavours were seen as either "too academic" or "too idealistic".

Interestingly, the result from table 2 shows that scepticism against the harmonisation infrastructure is most compact amongst academia respondents, in spite of the fact that some other respondents have criticised the endeavour as being too focussed towards the academic sphere. Instead, the results infer that support is rooted to a greater extent among policy-makers. This could indicate that harmonisation is seen as more politically than academically pertinent. Among the industry respondents, the views on harmonisation were surprisingly even-balanced with a slight margin in favour. Those in favour tend to cite the potential of reduced bureaucracy and a more seamless means of collaboration. Those opposing harmonisation tend to cite ownership issues, perceived lack of relevance, management concerns or practical feasibility. Ultimately, the results show that the industry stakeholders are very fragmented and diverse in their perceptions, both in terms of support, and their reasons behind it. The respondents representing the academia and policy-makers, on the other hand, appear to be consistent

and unison in their convictions. One of the main points of this study was to discern if there were any common themes present among the stakeholders' views or if they were all individually case specific (Donaldson & Preston, 1995). While this study can surmise that there were some recurring phenomena present among several different stakeholders, it is important to remember that there is no universal solution that caters to all respondents and that individual approaches must be taken to address each of the stakeholders. Yet, on a more specific level, the results of this study indicate that an organisation such as BBMRI should consider focusing more on addressing stakeholders in the academia sphere while also reaching out to the industry.

LIMITATIONS OF THIS STUDY

It is important to remember that the selected interviews only represent a sample of different actors currently involved as potential stakeholders in the biobanking industry, and thus no generalisations should be inferred on a whole. It is also important realise that although the respondent as a representative is answering on behalf of their organisations, it is ultimately their own personal reflections that are in question rather than the official stance of the organisation they represent (for which reason the respondents have all been anonymised). Another limitation is the risk of the "interviewer effect". This entails that the interviewer directly or indirectly influences the respondent. By the same token, there is also a risk of garnering "prestige bias". That is to say that the respondent may perceive questions concerning their prestige as "loaded". This may lead to some exaggerated responses that do not accurately reflect reality. Furthermore, the results of this study should not be generalised or inferred analogously on other cases. Any results generated should be seen as solely representative for the participants within the scope of this study.

RECOMMENDATIONS FOR FUTURE RESEARCH

A suggestion for future research may involve an investigation of how BBMRI's governance structure affects the stakeholders' activities, such as the propensity to invest more time and/or resources in the infrastructure. An additional topic may involve how to formulate a strategy that address the concerns of stakeholders both on an individual level and on a general level.

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