Governance for Responsible Innovation

GREAT – 321480

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1. Executive Summary

This report is part of GREAT's Work package 3 (Context of Responsible Innovation) and presents the findings from a field trial. In this empirical exercise some of the project's preliminary results ('sample output'), namely the ten parameters, their descriptions and related analytical questions that are part of GREAT's current version of the Analytical Grid have been evaluated by help of a case study.

The project being studied is 'SNIFFPHONE'.[1] This project, which is funded through the EC's Horizon 2020, aims at developing an appropriate ICT solution such as, a smart phone application, for the early detection of diseases from exhaled breath. SNIFFPHONE started 15th February 2015 and is scheduled to take three and a half years. Through an analysis of the project's documentation (including the preceding EC call) as well as three semi-structured interviews and one focus group with seven SNIFFPHONE project participants we have assessed whether and if yes, in which way and to what extent the project is conducted in a responsible way. Our main finding is that the SNIFFPHONE participants engaged in the field trial show a strong tendency of realising RRI in various ways.

Next, the results from this case study and further findings from previous empirical research in GREAT have been used to investigate whether the Analytical Grid itself is an appropriate tool for assessing RRI. Suggestions are made for refinements of amendments with regard to the following concepts and themes: reflexivity, and in particular second-order reflexivity; transparency; and tensions and dilemmas.

We conclude that the Analytical Grid is a necessary and useful tool for reducing complexity in analysing a project's RRI activities and attitudes (or lack thereof). However, the Grid also requires quite a lot of background knowledge about current discourses of RRI, including the multiple meanings of key terms. A willingness to engage with this complex background to some extent is required in order to conduct a context-sensitive analysis that does sufficient justice to the many characteristics of a constantly evolving international and interdisciplinary project such as SNIFFPHONE. Given the complexity of both project and RRI discourse it is important to remain aware of the limitations and possible blind spots of the RRI analysis conducted.

2. Introduction

GREAT aims at developing an empirically based and theoretically sound model of the role of responsible research and innovation (RRI) governance. A crucial part in the construction of this model is the 'Analytical Grid' (AG), a framework consisting of currently 10 parameters and related analytical questions, that are intended to help in assessing whether and if yes, in which way and to what extent a given project is conducted in a responsible way. The AG and its theoretical underpinnings have been explained in other deliverables (D 2.2 Theoretical Landscape, and D 2.3 Analytical Grid Report). Various steps in testing the AG and its underlying assumptions against

[1] http://cordis.europa.eu/project/rcn/194138_en.html; 16-08-2015.

empirical data have been undertaken to date (D 3.2 Exemplifying the Typology with Relevant RRI Projects; D 3.4 Context of RRI Report; and D 4.2 Case Study Report).

This report provides another important 'reality check'. The latest version of the AG is evaluated based on a field trial with a project in its inception phase. SNIFFPHONE started 15th February 2015 and is funded through the EC's Horizon 2020, and in particular the work programme 'ICT-02a-2014: Smart System Integration'. The project's aim is to find and develop an appropriate ICT solution such as, a smart phone application, for the early detection of diseases from exhaled breath. The current focus is on different types of cancer, and especially gastric cancer. The project is scheduled to run for three and a half years. The consortium consists of nine project partners from six countries: Israel; Germany; Finland; Austria; Latvia; and Ireland. Four partners may be classified as 'SMEs'; two as 'institutions for higher secondary education'; one as a 'research institute', and one large company may be considered an 'industry' partner.

Originally, this report was also supposed to include an evaluation of first key guidelines of RRI developed in GREAT's WP 6 (see GREAT's DOW, Workplan table, p. 12). However, the guidelines were still work in progress at the time of conducting the field trial, its analysis and write-up. So we could not include any such evaluation in this deliverable.

The empirical approach is different compared to D 3.2, D 3.4 and D 4.2, in that an analysis of relevant project documents is *combined* with the findings from semi-structured interviews and one focus group (with altogether seven different project participants). Also, most of the project documents used in the subsequent analysis are confidential and not publicly available. In this regard the report at hand differs from D 4.2. Whilst these methodological aspects are explained further in section 4, it is worthwhile considering the implications of such a high degree of confidentiality and the combination of methods. On the one hand, compared to the other case studies in GREAT the approach allows for understanding more facets of a given project (as they show in formal, written as well as informal, verbal accounts), which also helps to develop various perspectives on RRI in the project. On the other hand, the analysis presented here needs to be much more selective and may miss out on a few RRI aspects, as the field trial partner understandably requested a far-reaching non-disclosure agreement. This prevents us from going into any scientific, technical or commercial details. Yet, previous research has shown that 'responsible behaviour' can be distributed over various actors, as well as technological components or scientific equipment (cf. Latour 1994: pp. 5-6). Thus, any such hidden, indirect or 'networked' aspects of responsibility in SNIFFPHONE could not be analysed. This is a shame but also not surprising: non-disclosure agreements are very common, so the RRI analysis has actually been conducted under realistic conditions.

3. Objectives of the field trial

Two years into GREAT the field trial is a means to test some of the project's preliminary results ('sample output') in a real world case study (DOW, Workplan table, pp. 12-13). More precisely, the objective is to evaluate the Analytical Grid (AG) against empirical findings about SNIFFPHONE

which has already been introduced in section 2, and will be explained further in the subsequent sections.

Based on GREAT's D 2.2 Theoretical Landscape a first version of the AG has been developed and explained in D 2.3 Analytical Grid Report. Amendments to this first version have been in D 2.4 Responsible Innovation Models Report. This latest version of the Grid may be considered GREAT's current model of RRI, which is likely to undergo further iterations towards the end of the project.

The Analytical Grid, as summarised in figure 1, includes ten parameters that can be used for assessing to what extent, and in which ways a project is realising RRI. The table corresponds to a table already presented in D 3.4 Context of RRI Report (pp. 16-17). However, two additional parameters – anticipation and responsiveness – as discussed in D 2.4 have also been included.[2]

No.	Parameter	Description (research questions, analytical steps)
1	'Anticipation'	What is the (implicit) 'Weltanschauung' (vision of the world) of the project? What is the (implicit) relationship with the future?
2	'Product'	What kind of product does the project intend to create? What are the product's ethical implications? What are the reasons behind providing the product?
3	'Tools'	Does the project include tools for maintaining and enhancing reflexivity (and in this sense, an ethical approach)? If yes, what are these? In studying the empirical data we try to identify tools such as, an ethical board/committee, ethical review, or comparable organisational units and practices.[3]
4	'Process'[4]	Does the project include procedure(s) to pursue reflexivity? And an adequate level of participation?
5	'Epistemic Tools'	Does the project implicitly or explicitly rely on risk assessment (only)?[5] Alternatively, do the project participants follow the precautionary principle (only)?[6]
6	'Assessment'[7]	In which way are the technology and the project's results being assessed? Does this assessment involve any reflexivity? If yes, does this reflexive process involve a general normative horizon, or is it only concerned with technological developments or profits?
7	'Participatory	In which way has participation (inclusion of external stakeholders) been

[2] Also, the description of the parameter 'Assessment' has been adjusted slightly, as compared to the summary provided in D 3.4: all three questions have been changed to present tense. This reflects better the description provided in D 2.3, p. 87.
[3] Most of the examples listed here are actually also governance bodies.
[4] This parameter overlaps with the parameter 'Tools', and also with 'Participatory Approach'.
[5] As has been argued in D 2.3, pp. 84-85, risk assessments may be conducted in a quantitative way (based on mathematical calculations) or qualitative way. Both types would not be sufficient for assessing the impact of a system on society.
[6] D 2.3, pp. 85-87, includes a comprehensive discussion of the precautionary principle. For instance, it is argued that the precautionary principle often lacks a basis in ethical values.
[7] This parameter overlaps with the parameters 'Tools', 'Epistemic Tools' and 'Process'.

	Approach'	realised in the project? Five levels of influence may be distinguished when analysing the empirical data: Manifestly Absent – *Spectator* Ambiguously Absent – *Commentator* Medium – *Influence* High – *Co-construction* Too High – *Binding*
8	'Cultural Differences'	Does the project take into account cultural differences (of any kind, such as, different organisational cultures)? If yes, in which way?
9	'Norm/Law Relation'	Is the project only driven by laws or also by other norms? If yes, what kind of normativity is pursued? Norms possess a power for action that cannot be limited to a legal commitment.
10	'Responsibility'	How is responsibility conceptualised? Possible conceptualisations include: - liability/blameworthiness - care - responsiveness - accountability

Figure 1: Summary of the ten parameters of the Analytical Grid

By applying as many of these AG parameters as possible to the information gathered about SNIFFPHONE, we help to confirm, amend or refine the Grid.

4. Methodology

For realising the field trial the following empirical activities have been undertaken (cf. D 3.1 Fieldwork Methodology Report, pp. 5-7):

- document-based analysis (including the Horizon2020 work programme to which the project responds; parts of the project's research proposal and the description of work (DOW) as well as a draft of one project deliverable);
- interviews and focus group discussion (Krueger/Casey 2000) with SNIFFPHONE project participants (including two representatives of the project coordinating institution Technion):
    - three semi-structured interviews with five different project participants (one individual interview and two group interviews with each two project participants);
    - one focus group with four project participants (including two participants that have been interviewed previously).

The interviews and focus group were conducted via Skype, and took approx. one hour on average (for instance, the shortest interview took 41 min., the focus group took 1.15h). Next, the recordings were transcribed selectively.

The field trial has been conducted early in the design phase of SNIFFPHONE, as suggested in a previous deliverable (Fieldwork Methodology Report p. 7; Leroy 2011: pp. 4-5). It was not possible to conduct participant observation or video analysis given the time scales of both GREAT and SNIFFPHONE that needed to be coordinated. However, the interviews and focus groups provide a sample with various first helpful insights. For a more comprehensive and reliable RRI analysis interviews and focus groups with further project participants, and also an iterative analysis at various points in time over the course of SNIFFPHONE would be necessary. There is a lesson to be learned from our own field trial though: such a more comprehensive and iterative analysis is hard to realise, as there are various constrains (time, financial resources) any individual, team or organisation conducting an RRI analysis faces in reality.

One of the consortium members of SNIFFPHONE is VTT, which is also a member of GREAT. Veikko Ikonen from VTT helped in arranging the field trial with SNIFFPHONE. On the one hand, this means that our field trial is biased: to some extent we observe a reality that has been 'prepared' by us, so it is likely that we investigate activities and attitudes towards RRI that reflect our own project's (normative) stance from the start. On the other hand, it is also true that VTT is an example for an organisation that has learned about, and investigated RRI in another project (GREAT) and is now making use of these experiences in a new EC funded project. This is desirable from an RRI and EC perspective. Similarly, *we*, the authors of this report (UOXF), have learned more about RRI through engaging with SNIFFPHONE. Also, one of the SNIFFPHONE participants mentioned after the field trial that the exercise and its subsequent analysis as provided in this report were not only a matter of distant observation of extant attitudes and activities in SNIFFPHONE, but a way of 'instigating' (promoting) RRI further among the SNIFFPHONE members.

In sum, VTT's and our own engagement may be considered action research (Greenwood/Levin 2007). Moreover, as known in qualitative research, semi-structured interviews and focus groups are social interactions that do not (only) mirror reality, but also create something new in the field studied.

The consent form and two interview schedules are shown in Annex 1 and 2. Not all questions could be asked as it was also often necessary to follow the flow of the interviewees' responses, and to understand better the context of the issues they raised. This is in line with semi-structured interviews geared towards the methodology of ethnography (Spradley 1979).

In the subsequent sections all quotes will be anonymised, which includes no mentioning of the type of project partner being quoted. One interview was conducted in another language, so the related quotes have been translated into English. However, we will not identify these translated quotes in order to ensure anonymisation.

5. RRI assessment of SNIFFPHONE based on the Analytical Grid

In the following subsections SNIFFPHONE is analysed by comparing the empirical data gathered to the ten parameters of the Analytical Grid as summarised in figure 1 (section 3). For a coherent

description of the case we have changed the order of the parameters. We start with the parameter 'product', as this provides for a good introduction to SNIFFPHONE.

5.1 Ethical implications of the product

No.	Parameter	Description (research questions, analytical steps)
2	'Product'	What kind of product does the project intend to create? What are the product's ethical implications? What are the reasons behind providing the product?

At the time of the field trial the product to be developed by the SNIFFPHONE consortium cannot be fully specified. The project's basic aim is to develop an ICT solution for the early detection of diseases from exhaled breath. As the project name suggests, one important vision is to provide this solution in the form of a portable device such as, an application for a smart phone to be used by 'laymen' in everyday life, like any other kind of smart phone application. However, the consortium also appears to be open to alternative products such as, a device exclusively developed for, and adapted to the clinical setting or a general practitioner's surgery. Similarly, the range of diseases to be targeted has not been fully specified. The project's current main focus is on gastric cancer, but other cancers are not (yet) excluded.

Accordingly, the possible ethical implications are numerous, depending on the further development process. The interviewees mention various possible issues. In part they have learned about these issues through their consultation activities, i.e. semi-structured interviews with clinical experts. This shows in the first two of the following three quotes:

'Based on the interviews we have conducted so far the main ethical concern relates to the generation of false positives – when the test of an individual's breath results in a false positive, and the person gets told by the phone: 'you have gastric cancer', but this isn't true. As with all false positives this creates emotional distress. In case of a smart phone approach where the test is conducted at home the individual would face the result without any further medical contextualisation. A doctor would never make such a diagnosis based on a smart phone test only. Instead, he would consider the result in relation to other medical diagnoses. Suppose the individual makes the test at the doctor's, the doctor would immediately arrange for a gastroscopy, in order to see whether the test result is correct. Of course this wouldn't be possible for people using the device at home. So there are major ethical concerns about permitting the sniffphone's use at home.'

'Another issue that has been raised in the interviews [conducted by SNIFFPHONE partners] is an [excessive] awareness of ill health that will be created, as you are supposed to conduct the test repeatedly. This may put strain on the individual – it occupies your mind.'

'The data is processed throughout several ICT platforms, and then it goes back to the clinical doctor, who will decide how to manage the positive alarm. We are against, at least personally I am against the fact that the [individual smart phone] user would see the result, he should just have the input inside the device but shouldn't be involved with any direct results. So there has to be intermediate personnel, which is the doctor or [...] the staff of the hospital, so the exact definition of this staff we have to define [...] And of course this is not trivial. [...] We may have some issues with the insurance companies [who would want to use the data for making their predictions], or we might have some ethical issues with the overload of the

work with the clinical doctor because he will be responsible of thousands over thousands [individual data sets]. So we want to know where we'll send this data exactly. Of course not to the user. So this is one of the dilemmas we are examining these days.'

The consortium has developed different usage scenarios for the envisaged device. At the time of the field trial these scenarios were part of the semi-structured interviews the consortium conducted with different clinical experts (external stakeholders). Due to the NDA we cannot specify these scenarios further. However, it may be argued that each scenario has different implications for data privacy, that is, they appear to imply different answers to, for instance, the following questions:

- Who would have access to the data of a person's breath being analysed?
- What exactly is this data about?
- For how long would the data be stored, if at all? And where?
- Could or should the data be combined with other data, and if so, what kind of data?
- How would the data be analysed, and by whom?

However, as mentioned previously, in this RRI analysis we can hardly pin down any such potential privacy issue, as more detailed information about the *kind* of device that is envisaged in each scenario is (still) missing. For instance, the following questions cannot be answered at this point in time:

- What kind of material would the device consist of?
- How big is it?
- How does it look like?
- Does it have a particular user interface, and if yes, how does it look like?

According to some project participants', this vagueness is as much unavoidable as it is also, in a certain sense, desirable: the product's features, functions and measures are still very much in the making, depending on the feedback obtained through the expert interviews mentioned, as well as a broader survey to be conducted later in the project. Also, the consortium partners' own understanding of appropriate and desirable use contexts, and hence of device's exact design, appears to be evolving. Importantly, the consortium partners interviewed for this study show a strong propensity to discuss their evolving understanding of both device and usage context among each other, thus engaging in internal deliberations.

Apart from the ethical concerns discussed so far, one interviewee made it very clear what the (ethical) *benefit* of the future widespread usage of a device for the early detection of diseases would be. This may be considered one of the main reasons behind the envisaged product: the detection of serious diseases as early as possible in order to improve the patient's treatment, and to increase the chance of his or her survival.

'[The aim is to develop a device for] every user based on daily life. And the rationale behind it is that most of the cancers, and the diseases, are detected in advanced stages. [But] at the time they [already] do exist in our human body we feel healthy. We don't feel any side effects. [...] We don't have [yet] any technique to diagnose it. And therefore we cannot just go to the clinical doctor and claim that we want this examination, or another.'

Thus, while there is a strong supposed 'ethical' reason behind the development of a device for the early detection of diseases, there is still a long way to go in finding an appropriate solution.

In sum, the current project situation appears to correspond to the Collingridge dilemma (Stilgoe et al. 2013: p. 1569). The nature of the innovation, or innovative product, and its ethical implications, depend very much on how this very product is still to be developed over time. While the development process could best be changed in the early stages by taking into account any ethical considerations, thus preventing any potential later societal harm, it is precisely this potential harm that is very hard to specify at the early stages. Yet, the empirical data also suggests that there is an active debate, and deliberation process among SNIFFPHONE project participants who try to specify the envisaged product and its ethical implications incrementally, that is, over the course of the project, and to develop appropriate safeguards or alternative solutions accordingly.

5.2 Reflexivity (parameters 'tools', 'process' and 'assessment')

In this section three parameters are combined that all include a variety of questions related to reflexivity: are there any tools, processes, and in particular, assessment procedures that involve and enhance reflexivity, and if so, in which way(s)?

No.	Parameter	Description (research questions, analytical steps)
3	'Tools'	Does the project include tools for maintaining and enhancing reflexivity (and in this sense, an ethical approach)? If yes, what are these? In studying the empirical data we try to identify tools such as, an ethical board/committee, ethical review, or comparable organisational units and practices.
4	'Process'	Does the project include procedure(s) to pursue reflexivity? And an adequate level of participation?
6	'Assessment'	In which way are the technology and the project's results being assessed? Does this assessment involve any reflexivity? If yes, does this reflexive process involve a general normative horizon, or is it only concerned with technological developments or profits?

The concept of reflexivity has been discussed extensively in D 2.2 The Theoretical Landscape (e.g. p. 74), and it can be summarised as follows (cf. D 3.4 Context of RRI Report, p. 15):

- A system's capacity to adapt and change its state.
- Researchers and innovators thinking about their own ethical, political or social assumptions (framings) implicitly guiding their work.
- Researchers and innovators take responsibility for their framings.[8]

[8] Given the second bullet point reflexivity is also, in part, related to participation. For instance, one may start questioning one's own (taken-for-granted) assumptions, or framing, when confronted with other stakeholders'

One internal project document, the project proposal, includes a comprehensive explicit discussion of an RRI approach to be pursued in SNIFFPHONE. Due to the proposal's confidentiality (as specified in the NDA) we are not allowed to quote any content. However, the following conclusion can be drawn: we haven't seen any such comprehensive mention of, and elaboration on RRI tools and approaches in any of the other projects studied in GREAT to date (cf. D 3.2, D 3.4 and D 2.4). SNIFFPHONE has been conceptualised in a way that it is meant to be driven by various 'tools', 'procedures' and 'processes' as indicated under no. 3 and 4 in the above AG parameter table. Also, the understanding of reflexivity, and RRI, included in the project proposal is very much in line with GREAT's own interpretation. A possible explanation for this is a 'spill over' in knowledge and discourses from GREAT to SNIFFPHONE, as one GREAT project partner, VTT, also became a member of the later built SNIFFPHONE consortium.[9]

An important point to highlight here, though, is that this strong RRI approach in SNIFFPHONE has been identified based on *formal documentation*. As has been argued elsewhere, documented reality and (alternative) project realities made visible through other methods such as, semi-structured interviews, can differ significantly from one another. In the worst case, formal documentation can function as a 'ceremonial' false front, presenting a project in a very favourable light (cf. Meyer/Rowan 1977: 341; cf. D 2.4 p. 57).

So what does the other empirical data – the interviews and the focus group – reveal about SNIFFPHONE's take on reflexivity? Do these other sources contradict, support or in any other way complement the positive impression gained through the document analysis?

The interviewees do reflect on various ethical issues, as already outlined in the previous section, and they also show a willingness to change the course of the project based on feedback from external stakeholders gathered through various empirical activities (the semi-structured expert interviews and the survey, as mentioned previously, but also through a clinical trial). Their reflections go beyond the official ethical review process of the EC.[10] Also, the reflections clearly involve a general normative horizon, which does not exclude, though, an interest in the pursuit of commercially desirable options. In other words, based on some interviewees' comments it may be argued that contrary to what the parameter 'assessment' suggests, it may be possible to strike a balance between technology development and profit-seeking on the one hand, and a general normative horizon on the other. For instance, one interviewee explained that developing a device that would remain with the doctor in a clinical setting, instead of pursuing further the smart phone vision, would match well his organisation's existing commercial activities. Yet, he also emphasised that any such alternative product development would be based on sufficient empirical evidence derived from SNIFFPHONE's interviewing process, a view shared by another interviewee:

assumptions, framings, views and interests. This link between reflexivity and participation is indicated by the 'Process' parameter.

[9] For further discussion of this point, and its methodological implications for this RRI analysis, see section 4.

[10] One project participant explained that the EC did not provide any feedback on potential ethical challenges. He said he would have appreciated such an exchange of ideas and experiences in order to improve SNIFFPHONE and future projects.

'That's the purpose of the interviews: identify hidden needs. If we already knew these we wouldn't have to conduct the interviews in the first place. But then our design would ignore the client.

This view, which reflects a readiness to change the course of the project depending on external stakeholders' feedback, is strongly shared by other project participants. More precisely, VTT appears to play a key role in driving a comprehensive RRI approach in the project.[11] VTT's role in the project actually resembles the function of 'embedded' social scientist as described and promoted in STIR (Socio-technical Integration Research; Fisher/Rip 2013: p. 174). Importantly, the empirical data suggests that VTT is not a 'lone warrior' in the project (see next quote), and also gets challenged by other project participants in what seems to be a productive, engaged exchange of knowledge and ideas, and thinking aloud. All this appears to be part of a process of mutual learning (second quote).

'We are indeed, to some extent, concerned with ethical and security aspects. [...] As you may know VTT's work focuses a lot on ethical aspects'. [...] We do keep in touch with them. [...] And when we come across any specific issues in our interviews, of course we inform them about these, including ethical and security issues.'

'I think the critical important issue is the different principle of the maybe data transmission or the result transmission and I probably accept that VTT has really very good knowledge on this and maybe I shouldn't comment on this but at least what I understand from the clinical perspective and we have had a couple of meetings as well with special lecturers, everybody really is concerned on the new EU legislation concerning the personal data safety. And since we consider also the volatile marker results, some kind of medical data that are transmitted over the phone or in the public IT system, so I think these are really critically important issues - how really we are dealing with these. For instance, laboratories they need to code their data, with specific ways to en/uncode them and I think these are critical important issues because in this case, even if this is the data, the results are transmitted through the mobile phone, in this case also the mobile telephone operator and many other players in between the chain might have theoretically at least access to the data and I think this is one issue, and a very different issue is how the results are coming back to the individual that is being tested. Whether it is some centralised site, maybe for the screening that might be a centralised screening facility, in this case probably the key stakeholders would really be the centralised screening facilities that are gathering the data. And how the results are being reported back to the individual, in what way, whether they are given maybe through the general practitioner, through the GP in this case once more this is becoming involved, or they are transmitted through the phone that could be a reasonable way because then the results are at least transmitted or it's quite guaranteed that the results are given back to the individual. So what I understand with all the stakeholders these are a very big number of stakeholders depending on the scenario, how the data will be transmitted". [...] But I haven't got a ready recipe how to deal with all this.'

This quote also includes reflections on the vast amount of different stakeholders that appear to be directly or indirectly affect by SNIFFPHONE. This will be discussed further in the next section.

[11] VTT's role in SNIFFPHONE is discussed further in section 4.

5.3 Participation

No.	Parameter	Description (research questions, analytical steps)
7	'Participatory Approach'	In which way has participation (inclusion of external stakeholders) been realised in the project? Five levels of influence may be distinguished when analysing the empirical data: Manifestly Absent – *Spectator* Ambiguously Absent – *Commentator* Medium – *Influence* High – *Co-construction* Too High – *Binding*

The project is still at an early stage. At the time of the field trial the SNIFFPHONE partners were in the process of designing and refining schedules for semi-structured interviews and a survey. Some first interviews had already been conducted with, for instance, oncologists and gastroenterologists.

So far the interviews and survey appear to be designed for engaging mostly with medical experts (but at least one interview has also been conducted with a statistician). At first sight, this suggests a rather narrow participatory approach, as there are also a number of other potential stakeholders as mentioned in the previous section. These are, for instance, laboratory personnel and, as one interviewee put it, "the mobile telephone operator and many other players in between the chain" of data being transmitted from a given smart phone to a central place for data analysis.

However, the project is still very much evolving, and this appears to also apply to the project's participatory approach. Various interviewees emphasized that a 'human-centred design' approach would be at the core of the project. As one interviewee put it, 'human-driven design will definitely go on all the three years [of the project].' In a similar vein, the following quotes suggest that there is an overall awareness among the interviewees that the project is complex, and challenging, in terms of various stakeholders being affected directly or indirectly. Project participants seem to reflect on stakeholder issues and, in principle, ready to engage with different stakeholders as far as this is feasible in the project's timescales, as the next quotes exemplify (emphases added).

'There are basically two opposing stakeholders: the *scientific community* wanting to derive major principles from the knowledge they acquire [...] I'm talking about the final future use of the final device, so one would be the scientific community trying to acquire the basic principles trying to figure out which gases are good markers for which states for which cancer and so on, and the other one would be *the individual* seeking help and trying to maintain its privacy while doing so. And I think the balance between these two would be the gathering of general information from the central server only in an anonymous form and only in a way that would allow the individuals to maintain their privacy and another big ethical question would be *insurance companies*. Where - would it be okay for them to ask individuals to go for a

sniffphone trial and then you know decide or determine their likelihood of developing cancer in the future and really dictating their payments accordingly. So that would be maybe the third stakeholder.'

'[For the interviews] we have mostly been searching for *experts*. [...] The group for the survey – that's still a matter of discussion. For instance, [another consortium partner] got in touch with [the *civil society organisation* x] and further organisations, and we might be able to run the survey with their members, or people who attended these organisations' conferences. But this is still very much in the making and not ripe for decision.'

'We also have to take into consideration things that are in the pipeline with *big companies* or *VCs* [venture capital firms or funds]. [...] because VCs or big companies have always different modes of thought.'

In sum, the project appears to have a potential for reaching a high level of participation, possibly even moving beyond 'influence' towards 'co-construction', as suggested by the parameter's scale.

5.4 Risk assessment (parameter 'epistemic tools')

No.	Parameter	Description (research questions, analytical steps)
5	'Epistemic Tools'	Does the project implicitly or explicitly rely on risk assessment (only)?[12] Alternatively, do the project participants follow the precautionary principle (only)?[13]

The interview data suggests that no participant tends towards a simplistic understanding of project 'risks'. Interestingly, this is true despite one interviewee's repeated use of the term. However, the *contexts* and the *ways* in which he used the term suggest that there is no understanding of 'risk' as, for instance, financial risk only; as something to be solved through extensive quantitative calculation; something to be entirely delegated to other experts; or as dimensions of the project to be separated from any questions of ethical or social impact (D 2.3, p. 85). Instead, the interviewee and the other project participants quoted in the preceding and subsequent sections often show a holistic understanding of ethical and social issues being interwoven with the technological aspirations of the project.

5.5 Anticipation

No.	Parameter	Description (research questions, analytical steps)
1	'Anticipation'	What is the (implicit) 'Weltanschauung' (vision of the world) of the project? What is the (implicit) relationship with the future?

Data from one interview suggests that the project's main vision is to build up 'big data' sets, and harness 'big data' analytics in understanding, diagnosing or predicting an individual's health. This is part of a growing trend worldwide, entailing, for instance, hopes for improvements in the early

[12] As has been argued in D 2.3, pp. 84-85, risk assessments may be conducted in a quantitative way (based on mathematical calculations) or qualitative way (based on more personal expert opinions). Both types would not be sufficient for assessing the impact of a system on society.

[13] D 2.3, pp. 85-87, includes a comprehensive discussion of the precautionary principle. For instance, it is argued that the precautionary principle often lacks a basis in ethical values.

diagnosis of diseases, in care, and also for reducing health care costs (Marr 2015; Health Data Alliance 2015). The interviewee in question shows an awareness of the possible difficulties associated with realising this vision such as, a high risk of interpreting data incorrectly:

'To analyse these results [from individuals' breath detection], it's not trivial. And there might be professional challenges for the clinical doctor or for the technician to make this analysis. Because this analysis will be inside a very large pool of data [in] which you need to compare the specific data of this person with his own history, similar signals, and with other people and with many other confounding factors'.

Further interview data suggests that the project tries to keep a balance between, on the one hand, understanding and learning from present experiences and expertise in health-related ICT, and understanding and learning from future prospects on the other. This constant tightrope walk between the (evolving) present and possible futures appears to be conceptually interesting. It is some sort of highly dynamic anticipatory practice, i.e. a practice of innovation that is very much geared towards a certain imaginary of future society – a society organised around 'big data' – and the attempt to nevertheless remain rooted in the present. This dual approach appears to be a necessary response to the structural problem that ICT developed during a project lasting three or more years often face: they are at a high risk of being outdated already at the end of the project, given the rapid changes in the global ICT landscape.[14]

'Of course [big companies like Google] have their own opinion regarding what will be in the future within five or six years, and how we can integrate in the future with their platform. It's very important right now to understand that this [SNIFFPHONE] device will not be available for three and a half years from now. And therefore we have not only to plan what is already existing right now in the current infrastructure world-wide, but rather we also have to take into consideration things that are in the pipeline with big companies or VCs et cetera et cetera. I know this is a complicated issue but we have to consider it, even though practically we will rely on whatever we have right now and is well established right now. But of course for analysis we have to take what other things there will be in digital health in future. So we have to find the balance."

Another important vision of the project is the following: to contribute to the development of a portable device that, at some point in the future, could be used all around the world, and especially in developing countries. One of the interviewees elaborates on this vision as follows:

'When you don't have a centralised healthcare system in that sense that in every village [...] you have a kind of an army of health care professionals; and in the places where people are living in a scattered way, so there is a long way to the physical doctor - so you could utilise this kind of system where you measure something from you and then the data is going to be analysed somewhere else, and then you would diagnose that somewhere else - and then if there is a need to proceed then you are invited to go to a place where you can have a physical treatment or physical interaction with the doctor or nurse.[...] This is just some example how breath samples could be utilised, so gastric cancer was the main example here but it could be something else, but the issue was that maybe then gastric cancer is not anymore an issue in western countries, it's more relevant in Africa and Asia [...] those were the issues we were discussing [in previous SNIFFPHONE meetings].'

[14] This point was also made by another interviewee from another project that we included in our earlier empirical analysis in D 3.4, Context of RRI report.

Whether this vision for developing countries is linked to concrete project activities, and if so, how, will be discussed in the next section.

5.6 Cultural differences

No.	Parameter	Description (research questions, analytical steps)
8	'Cultural Differences'	Does the project take into account cultural differences (of any kind, such as, different organisational cultures)? If yes, in which way?

As explained in the last section one of the visions of the SNIFFPHONE project is to possibly develop a device that can be used for the early detection of devices in developing countries. The project participants appear to have started to collect information (see next quote), and also to reflect on the numerous cultural issues that would arise from ICT development for so many different countries, acknowledging that developing a good understanding of these multiple potential contexts of usage is still a challenge. This also applies to countries within Europe (see second quote):

'We [are] involved in the second questionnaire, in general, collecting the viewpoints of experts actually globally [...] and a lot of the questions of the questionnaire no 2 are actually addressing these issues, what the specialists consider acceptable, what really would be reasonable for different countries with different [...] background and maybe disease information.'

'It's a big issue of course if you try then to implement this kind of system to another context or even in our western context you have lots of issues - so it's just an idea to find some broader usefulness for this kind of application but of course we haven't discussed about it, of taking into account more detailed issues related to context. [...] It is still quite challenging.'

Interviewees also report on other cultural issues within Europe that they need to take into account in the development process: different perceptions of what an acceptable 'business model' in health care is (first quote). Moreover, intra-European cultural differences affect daily work significantly such as, the need to translate between the different languages spoken by different project partners, and the need to understand medical expert language – both these issues also appear in combination, which complicates project work (second quote).

'There might be cultural differences already in the business model. [For instance,] In Germany there is very much – uneasiness or worries about [developing such a] care device [for home use], so in Germany the business model would probably be much more accepted where the sniffphone is actually used by a medical professional. [...] Of course [this has implications for the project] because we are collecting all this information and feedback and this might definitely somehow also go into the design and the business models, and maybe there will be more than one model, I mean different models for different regions. That's all still possible'.

'I have to translate the [project] documents in [my language]. I'm not so expert in medical language – so coping with that problem – translating the medical language from English to [this other language] or vice versa, it could be a problem. And make some misunderstanding between the consortium. [...] [The clinicians] are speaking their own language, and when I'm not familiar with their language I just write it

down [...], [and then I do some research] and try to understand what they have said to me. [...] [Sometimes I also need to check:] is this really the right term I'm using?'

In sum, it may be argued that the project does attempt to take into account relevant cultural differences as much as this is possible within the project's timescale. Participants gather empirical data (e.g. the questionnaire mentioned by one interviewee) which may lead to changes in the technology design, and to different business models for different countries. They also engage in internal discussions (see the last sentence of the last quote in the previous section). Also, it is worthwhile acknowledging, from an RRI perspective, the cultural differences implied by conducting research and innovation in an interdisciplinary as well as international project such as SNIFFPHONE. As the last quote suggests, this entails everyday cultural work that shows in many details. This workload should not be taken for granted.[15]

5.7 Norms and laws

No.	Parameter	Description (research questions, analytical steps)
9	'Norm/Law Relation'	Is the project only driven by laws or also by other norms? If yes, what kind of normativity is pursued? Norms possess a power for action that cannot be limited to a legal commitment.

Various interviewees emphasized that there is a difference between two types of data gathering activities in SNIFFPHONE: the envisaged clinical trial, that is, the assessment of a prototype in a clinical setting, and the still evolving ideas about (possibly) evaluating this or another prototype with 'laymen' in everyday life circumstances. The latter includes different possible scenarios such as, population-wide 'screening' (regular prescribed health checks for the entire population) versus more individualistic usage. In drawing and discussing this distinction among themselves they show an awareness of the difference between existing formal legal regulation in one area (the clinical trial), which they may rely on and don't need to question, and the need to develop an ethically appropriate approach for the other, still much less specified and uncertain context of usage (e.g. individual smart phone use including breath detection 'at home').

This second context of use, which is still very broad and unpredictable, is what one interviewee refers to when elaborating on 'ethical issues that might be introduced in the technology by design', as opposed to the clearly circumscribed clinical studies (first quote). Another interviewee agrees (second quote).

'There is a difference between the ethical issues that might be introduced in the technology by design and the ethical issues around the clinical studies because for the clinical studies there are very clear and strict rules and standards, and this is really important, because there we really have patients and, while in the technology - [...] I think ethics by design is pretty new in the project, as an aim, and I think it should more like there is really an early discussion, also on a technology basis, whether the measurements, the analysis, the data storage, whether they can be improved to be more ethical. So in the technology it's more being

[15] This point resonates with our previous findings (see D 3.4 Context of RRI Report). EU project work implies 'cultural translations' in a variety of forms. From an RRI perspective we should not ignore these as they can significantly complicate a given project participant's everyday work, and ultimately require extra time and financial resources (e.g. person months).

early aware of ethical questions and be early able to discuss this and to implicate this already maybe in the design but this has to be more open to really be able to find different solutions. So I think there's a difference to the ethics in the clinical trial because in the clinical trial you have very clear rules and you need these very clear rules while in the technology part, I mean you are still in development so you need also some freedom of action, but of course if you include the ethics as early as possible in the design this also means that you don't need to change it afterwards.'

'Okay absolutely I agree and may I add an example here, because if speaking about SNIFFPHONE as a screening cancer tool, so in the [clinical] study definitely we would be asking for signed consent, on the other hand if we go out in the screening settings in the general public, so this is a critical issue to allow screening without asking for a signed consent, because if we have to ask for a signed consent for every phone user to the - practically what would we expect is that in [that] case the participant is committed to be involved in the system or I don't know buying the phone or signing with his GP and saying that he is willing to undergo some testing or some screening activities, in this case if we would be requiring signed consent from everybody this would substantially lower the participation in the programme [which significantly reduces the possibility of the early detection of a disease]. [...] So two distinct settings: clinical study vs. general public screening.'

While the two interviewees just quoted consider the clinical trial less challenging in terms of ethical issues, another interviewee went a step further and argued that the project needs to be responsive to participants' 'feelings' in the clinical trial too:

'My personal inclination is to allow as much freedom as we can to the actual participants, a) in the trials and b) using the final product to decide how much exposure they feel comfortable with in terms of who sees their results and why and when. But this is my personal view about this.'

All three quotes stem from the focus group conducted with four project participants. It is important to stress that the quotes provide only a glimpse of the comprehensive discussion of potential ethical issues that actually took place.

In sum, the project is not only geared towards complying with legal requirements and regulation. It is also very much driven by a preoccupation with individuals' varying concerns and needs related to a smart phone application (or a similar portable device) for breath detection.

5.8 Overall conception of responsibility

No.	Parameter	Description (research questions, analytical steps)
10	'Responsibility'	How is responsibility conceptualised? Possible conceptualisations include: - liability/blameworthiness - care - responsiveness - accountability

According to Pellizzoni (2004: pp. 547-548), 'liability' and 'accountability' are 'ex-post' concepts of responsibility: actors attribute responsibility to someone or something that has already

happened. Instead, 'care' and 'responsiveness' are considered more 'anticipatory' (ex-ante) concepts of responsibility. Furthermore, appealing to responsibility in the sense of 'liability' implies being geared towards a strong nation state, and its laws, rules and means to judge and sanction (ir)responsible behaviour (Pellizzoni 2004: p. 550).

As we have argued elsewhere, this understanding of responsibility as 'liability' corresponds to a 'negative' understanding of responsibility as 'compliance' with formal legislation and regulation (D 2.2 Theoretical Landscape p. 42, 52). Conceptually, 'accountability' shares these connotations of formal authority to some extent, but shifts the emphasis from central government to decentralised governance, 'going well beyond the limits of traditional political answerability'. This includes an implicit reliance on multiple, dispersed expert practices of auditing, i.e. 'forms of verification, evaluation, control and review' to ascertain whether behaviour is to be considered as responsible or irresponsible (Pellizzoni 2004: 550). However, as is true for 'liability' this is also a 'negative' conception of responsibility, since attention is mostly focusing on actors having to 'pay for the (possibly wrong) things they did' (D 2.2 p. 61).

According to the RRI perspective developed in GREAT, which heavily draws on Pellizzoni's approach, 'care' and 'responsiveness' are more 'positive and prospective' conceptions of responsibility. Actors are considered as active heedful agents of change that can be motivated to 'engage in a process through which they take care of others' (D 2.2 p. 61).

The concept of care can be understood can be explained by help of the metaphor of parents who (ideally) take forward-looking responsibility for their child which cannot yet fully grasp social reality and all the consequences of its own actions. Interestingly, there is also a potentially dark side to this, with the parents potentially considering themselves too knowledgeable and taking over too many decisions on behalf of the child. This dark side shows in Pellizzoni's point that the 'welfare state of the twentieth century' and the 'Hobbesian absolute state' resemble one another in that their 'relationship with citizens' would be 'similar to that of a good mother with her children, whose needs, desires, strengths and weaknesses she knows very well' (Pellizzoni 2004: 549).

'Responsiveness' differs from this implied absolutism in that the two (or more) parties involved in a responsibility relationship are considered to be on equal footing, in the following sense: they are both part of an ongoing interaction of mutual listening, trying to understand each other, and trying to respond to each other's concerns by, for instance, adjusting one's own attitude and behaviour. As Pellizoni pointed out, 'previous listening' is key to this kind of forward-looking responsible behaviour, in which neither party 'pretend[s] to know in advance' the needs and desires of the other (Pellizzoni 2004: 549).

It is this concept of responsiveness that GREAT considers one of the five basic principles of RRI, apart from transparency, anticipation, participation and reflexivity (D 2.2. pp. 71-76). Responsiveness is also a key concept in the RRI framework developed by Stilgoe et al. (2013).

The empirical data suggests that SNIFFPHONE's conception of responsibility is a combination of 'liability' and 'responsiveness'. On the one hand, various interviewees feel that in terms of the

clinical studies to be conducted within the project, the participants can rely on existing (medical) rules and regulations, or at least standards that have already been proven to be appropriate and are sufficiently recognised in health research. So in this regard they would not need to 'reinvent the wheel' for RRI. However, a greater part of the project is about exploring the opportunities and challenges with using a portable device for the detection of diseases from breath with *all* sorts of individuals (not only 'patients', as in the clinical setting) in all sorts of everyday life circumstances, including a 'chain' of different intermediaries involved in the detection, transmission and analysis of individual health data. It may be argued that these various nested contexts of technology development and use are still highly unchartered territory for the interviewees in terms of appropriate responsible behaviour. The way interviewees have talked about potential ethical and broader societal issues, and how to approach these based on external stakeholders' feedback as well as internal deliberation processes, shows a strong tendency towards a conception of responsibility as responsiveness.

It is important to keep in mind though that there may also be other conceptions of responsibility that are relevant for the SNIFFPHONE project participants, as the empirical data gathered and analysed for this field trial is a sample obtained at a certain point in time. Other project participants, and even the same project participants in other and later (interview) situations, might explicitly or implicitly deal with a broader spectrum of responsibility notions. For instance, our previous empirical research into the EU's FP7 CIP ICT PSP suggests that responsibility understood as 'accountability' may also be relevant. Some CIP ICT PSP project participants felt their actions need to be justifiable to national and EU tax payers (D 3.4 Context of RRI Report, p. 6, 48; cf. Sutcliffe 2011: p. 9).

5.9 Summary

The SNIFFPHONE participants that have been engaged in the field trial show a strong tendency of realising RRI in various ways.

The project is still at an early stage: exact outcomes or the exact final product are not yet specified. Accordingly, the product's ethical and broader social implications are relatively unclear. Thus, the situation resembles the Collingridge dilemma: if potential ethical or social consequences of the product could be specified better, the participants could take these into account more easily at the early stages of the project, i.e. at the beginning of the technology development cycle. Thereby any early 'closure' of the product that could be detrimental to society, and from an ethical point of view, could be avoided. However, to some extent and in some way such a closure (i.e. a more clearly defined, developed, already tested, used and evaluated prototype) is also necessary in order to develop a *realistic* understanding of any undesirable social and ethical consequences.

The participants appear to deal with this dilemma incrementally, that is, they build up knowledge and practical experiences in a step-by-step way. It may be argued that they consciously approach the project's activities, its potential outcomes and the final product as 'epistemic objects' which necessarily 'unfold' continuously (Knorr Cetina 1997: pp. 9-10). This happens partly in ways they

can know and influence, but also partly in ways they cannot foresee and they need to learn over time.

For instance, the participants show an ability to discuss and deliberate on various potential ethical and social issues that they can think of at this point in time not only individually but, importantly, also as a group, which entails the possibility of productive 'group think'. They also show a readiness to change the course of the project based on different stakeholders' feedback that they gather through empirical activities, including qualitative expert interviews and a survey. So far the focus in these empirical activities has been mostly on medical and clinical experts, but the participants also consider engaging with other relevant stakeholders in later stages of the project (for further details see section 5.3 on participation).

Thus, the project has the potential for reaching a high level of participation, akin to the governance model of 'co-construction', which may be considered an ideal way of realising RRI in practice (see GREAT's D 2.3 Analytical Grid Report p. 82).

In terms of three other parameters of the Analytical Grid – risk assessment, cultural differences, and the relationship between norms and laws – SNIFFPHONE shows promising initiatives, too. There is no indication that the interviewees have a simplistic understanding of risk, or risk assessment. Potential social and ethical issues are considered in close connection with technological issues, and it is within this context that the notion of 'risk' is used, without any downplaying of the complexity of ethics and social reality. Also, relevant cultural differences are taken into account as much as this is possible in the timescale of the project. For instance, there are ambitions to develop a portable device for the detection of diseases not only across Europe, but also in the so-called developing countries. In this regard the participants do not show any tendency towards a 'one-size-fits-all' approach. Instead, they are rather modest in what they believe can be achieved in a project's time. There are also concrete efforts (development of a survey) to understand different cultural contexts better through engaging with medical and clinical experts from all around the world. Finally, in terms of the parameter 'norm/law relation' we can state that the project is not only geared towards complying with formal legal requirements and regulation, but also very much driven by a preoccupation with the concerns and needs of all those individuals who might possibly use a smart phone with functions for detecting diseases in the future.

As mentioned previously, the project participants show a distinct tendency of reflecting on ethical and broader social issues (a 'general normative horizon'; see AG parameter 'assessment'). While one of the organisations in the consortium, VTT, formally and informally plays a key role in promoting a reflexive approach in the project, other partners clearly pick up on this initiative and also add their own constructive views. Various tools, procedures and processes for supporting reflexivity, and RRI in general, are listed and explained in SNIFFPHONE's research proposal. The data from the interviews and focus group suggests that project participants also genuinely strive for *implementing* these plans over the course of the project.

In terms of the parameter 'anticipation', at least two visions seem to be important to SNIFFPHONE:

(1) building a society, and health care systems in particular, that are organised around 'big data';
(2) improving the diagnosis of diseases in developing countries based on (commonly accepted) mobile phones. This also implies another general societal trend: realising the vision of the 'Internet of Things', and wearable computing worldwide.

In the project these visions manifest in highly dynamic anticipatory practices. The empirical data suggests that the project participants try to strike a balance between, on the one hand, understanding and learning from the *present* landscape of ICT as well as *current* stakeholder feedback and related possible changes to the project, and finding out about *future* trends in ICT to which they may also respond, on the other. A great deal of these future-oriented responses are most likely not be realised within the timescale of SNIFFPHONE though, but in follow-up projects. This paradoxical approach, that is, an orientation to future developments that are still hard to grasp, combined with making experiences that are rooted in the present and continuously emerge and unfold, appears to be complicated, and it is perhaps time-consuming. It also appears to be a reasonable approach though given the rapid changes ICT indeed undergo globally.

Finally, the overall conception of responsibility shared by SNIFFPHONE project participants appears to be a combination of 'liability' and 'responsiveness'. The participants distinguish between one part of the project that is relatively unproblematic in terms of established legal rules and procedures that need to be followed (clinical trial), and a much bigger and still much more unspecified, evolving part (individual usage of a portable 'sniffphone' in everyday life) that requires much more attention, thinking through, and learning with regard to appropriate security measures and ethical behaviour.

6. Evaluation of the Analytical Grid as a tool for assessing RRI

In what follows the findings presented in the preceding sections are reconsidered for an evaluation of the Analytical Grid. We also add further empirical insights into the context of SNIFFPHONE (the EC funding framework) as well as findings from previous research in GREAT. This leads to a number of suggestions for amendments to, or refinements of the Grid.

6.1 Elaborate on (second-order) reflexivity

The concept of reflexivity has many possible meanings. As Lynch (2000) pointed out, social action and interaction can actually be considered reflexive by definition; and considering somebody 'reflexive' is very much dependent on the (professional, disciplinary, methodological) context, epistemic community or community of practice in which he or she is being socialised. It is therefore hard to distinguish between different levels or degrees of reflexivity; it appears to be more appropriate to distinguish between different kinds of reflexivity.

These are considerations related to reflexivity that could still be built into the Analytical Grid. Also, the Grid could specify second-order reflexivity, one of the key concepts developed in

GREAT, and include a set of related questions (and perhaps further explanations or examples in some sort of background information attached to the Grid). In GREAT's D 2.3, p. 74, the difference between first and second-order reflexivity has been explained as follows (emphases added):

'In terms of RRI a first-order and a second-order reflexivity could have different meanings. However we could say that, considering an innovation (GMO, for instance) on which participants are called to express an opinion, a first order reflexivity would be a reflection on that specific innovation in its consequences, effects, need, etc. A second-order instead would require thinking about the same conditions that allowed us to think, and to think in a certain way. *What could it be the interest behind, who is financing the project, who settled the participatory structure, why,* etc. Of course this second-order could go from questions of a practical nature to more abstract and ambiguous matters as the discourse itself.'

For instance, addressing the point 'who is financing the project' requires an analysis of the original EC work programme and related EC policy documents to which the consortium responds. This could be considered a second-order RRI analysis which puts the RRI attitudes and activities observed at the project level into perspective.

So let us take a closer look at the EC call 'Information and Communication Technologies', and 'Smart System Integration' in particular. This is the call under which SNIFFPHONE has been funded.[16] For instance, SNIFFPHONE's comprehensive participatory approach is already implied in the following requirement:

'Work should develop along the full value chain and include validation of results in realistic environments and business cases'.

However, this requirement is not accompanied by any problematisation or provisions related to the actual challenges the implementation of a comprehensive participatory approach involves in practice such as, the huge amount of time required for actively engaging with the whole spectrum of relevant stakeholders. Is the EC funding institution aware of these challenges, and if yes, are these taken into consideration when evaluating the project? If yes, how does this happen, and how do these funders' judgements, in turn, affect subsequent RRI attitudes and activities at the project level?

Also, there are tensions built into the call that the consortium needs to handle in some way. For instance, fulfilling the following two requirements can become a task of squaring the circle if the interests, needs and concerns of industrial stakeholders, on the one hand, and prospective technology users on the other, that are still to be elicited and discussed further in the SNIFFPHONE consortium differ significantly (emphasis in the original):

'Work will be driven by *industrial requirements* and specifically target multidisciplinary R & D [...]. Work will be driven by *user requirements* and will target concrete solutions.'

[16] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/79-ict-02-2014.html; 13-08-2015.

Also, the overall objective of this call appears to be to 'establish European competitive ecosystems for the design [...] and industrialisation of [...] Smart Systems'. What are the implications of this economic eurocentrism for RRI? Could European competitiveness lead to the suppression of any existing or emerging initiatives of producing smart systems in, say, the developing countries? This could entail strong tensions in SNIFFPHONE's everyday project work (or a similar follow-up project), as the consortium has the vision of developing a 'responsible' portable device not only for European markets but possibly also for developing countries.

We have raised similar questions in previous research into the CIP ICT PSP, and provided insights into how EC work programmes appear to 'preconfigure' RRI at the project level (D 4.2, Case Study Report). Thus, it seems advisable to think about ways of including this second-order analytical perspective in the Grid.

6.2 Include transparency more explicitly

Transparency is considered one of the key principles of RRI, both in GREAT's previous deliverables (D 2.2 Theoretical Landscape p. 73; D 2.2 Analytical Grid Report p. 88) and the EC's own RRI framework.[17] However, the concept has not yet made its way into the core of the Analytical Grid, i.e. into the eight parameters as explained in D 2.2 (p. 83-87), even though it has to some extent been included in the extended version of the Grid presented in D 2.4 Responsible Innovation Models Report (as part of the definitions of the parameters 'Tools' and 'Process', e.g. pp. 10, 11).

GREAT's conceptualisation of transparency may be summarised as follows (D 2.2 p. 73; D 2.3 Context of RRI Report p. 15):

- Making available and distributing existing knowledge about a given technology, its consequences and forecasted uses.
- Making available and distributing the results of any related deliberation processes.

As we have argued already elsewhere, many partners in EU project consortia face a structural problem in realising transparency (D 3.4 pp. 9-10, 89-90). This also applies to the SNIFFPHONE consortium whose coordinator asked us to sign a comprehensive Non-Disclosure Agreement prior to our data gathering activities for the field trial. This is a very understandable request which any future RRI analysis targeting ongoing research and innovation processes is likely to face. Thus, we need to find a way of building a modest requirement for transparency into the Grid: any judgment of a consortium's apparent lack in transparency needs to be reconsidered against the background of a certain level and some forms of confidentiality required in a market economy.

This raises another interesting question though, which again touches on second-order reflexivity. Is there any way in which such systemic limitations in transparency could and should be challenged, pushing RRI and the Analytical Grid or similar assessment tools to another level,

[17] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation; https://ec.europa.eu/research/swafs/pdf/pub_public_engagement/responsible-research-and-innovation-leaflet_en.pdf; 13-08-2015.

namely a reconsideration of basic features of the market economy? This would require a huge concerted effort across multiple actors though, that is, a heedful form of collective responsibility. As Owen (2015: 5) has pointed out, such '*responsiveness*, particularly at institutional levels', 'present[s] considerable changes for implementation' (emphasis in the original).

6.3 Include tensions and dilemmas

The Grid does not include any assumptions or questions about potential dilemmas and tensions in a project; whether project participants are aware of these (and possibly even raise issues the RRI analyst was not aware of him/herself); and how such problems are dealt with. For instance, one interviewee argued that the project needs to tackle various 'dilemmas'. To summarise one of his examples: a potential future user of a portable 'sniffphone' should provide data about his or her state of health on a regular basis, but should perhaps not be burdened with receiving actual positive results since these can be very unsettling, and unnecessarily so in case a result turns out to be a false positive. However, shifting all the receiving, reading and interpretation of the results to, say, the GP or clinical doctor, could cause a massive workload for the latter, as he or she becomes responsible for monitoring 'thousands' of data points from numerous individuals.

Other important instances of dilemmas and tensions are those built into funding frameworks, as explained in section 6.1. We have made similar observations in our previous research into the EC's FP 7 CIP ICT PSP, where there are also dilemmas associated with other RRI principles such as, participation (e.g. D 3.4 Context of RRI Report, p. 110).

Conceptually, one could subsume the quest for dilemmas and tensions under 'reflexivity', a key RRI principle that has been translated into various questions across three AG parameters ('Process', 'Tools' and 'Assessment'). However, as argued previously this concept has multiple meanings which also require further considerations. It may therefore be sensible to introduce (and problematise, elaborate on) dilemmas and tensions elsewhere in the Grid, or in supporting background material.

7. Conclusions

GREAT's WP 2 has provided comprehensive and critical analyses of current RRI discourses, and these conceptual findings have been translated into a number of concrete parameters and questions that take little more space than one page, as shown in figure 1 (the Analytical Grid). This compact overview can be used as a lens for 'seeing' a project such as SNIFFPHONE in terms of its RRI activities and attitudes (or lack thereof). We consider this a useful reduction of an actual project's complexity.

However, and not surprisingly, reducing complexity risks missing or neglecting important points. We have shed light on some aspects that could be taken into account in the next iteration of the Grid. Reflexivity and especially second-order reflexivity may need to be specified further; transparency, and in particular the ambiguities attached to it, would merit further attention; and

tensions as well as dilemmas are not yet addressed by the Grid. Another important step would be to provide a more comprehensive comparison of the elements of the Grid with the European Commission's own 'five keys'.[18] On the one hand, there is considerable overlap, as already pointed out in one of our previous deliverables (D 4.2 Case Study Report, p. 7). Also, we have mentioned issues related to the concept of transparency that are crucial to both RRI approaches (see section 6.2 in this report). On the other hand, GREAT's Grid misses an RRI dimension that features prominently in the EC's guidelines: ensuring gender equality. Yet, it may also be argued that this dimension is implicit in the AG's parameter 'cultural differences', given that gender, and (supposed) gender differences, are socially and culturally constructed.

This leads to a final observation. The AG massively reduces complexity, but it also depends on many implicit assumptions such as, what to understand by 'cultural differences' or 'reflexivity'. In other words, the AG hides much more than it shows: a complex discourse of RRI, including various (possibly contesting) meanings of key terms. Thus, while the reduction of a project's complexity by help of the Grid is useful and necessary, conducting an RRI analysis of a given project may also require frequently going back to secondary literature and documentation of case studies or examples in order to better grasp the spectrum of RRI. This is why the provision of background material has repeatedly been suggested in the last section. We face a similar challenge in the development of GREAT's guidelines for RRI in WP 6. It takes considerable time to strike the right balance between comprehensive explanations of RRI from a conceptual and discursive point of view; the need to provide handy, easily understandable overviews; and the need to convey that every RRI analysis of a given project also needs to be tailored to the project's manifold characteristics, which often only emerge and also evolve over time.

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Annex 1: consent form

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Oxford

Consent Form
Governance for Responsible Innovation

Please read and initial those points below you agree with.

Please confirm your consent to participating in this research by signing the form below.

Initials

1. I confirm that the purpose of the study has been explained to me and I have had the opportunity to ask questions about the research and have had these answered satisfactorily. --------

2. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason and without any implications for my legal rights. --------

3. I am allowing the researcher to audio record me and take handwritten notes as part of the study. The recording will be transcribed. I understand that anonymised quotes may be used in presentations or publications stemming from the research but not in any way that might allow for identification of individual participants. --------

4. I am allowing the researcher to video record or photograph me as part of this study. Recordings will be transcribed. I understand that still images may be used in publications stemming from the research but that faces and other identifying features will be pixilated. --------

5. I understand the data will be kept confidential at all times. --------

6. I agree to take part in this research. --------

Name of participant:	Name of researcher:
Signature:	Signature:
Date:	Date:

If you have questions or concerns about any aspect of this project you may contact the principle investigator: Marina Jirotka, Oxford e-Research Centre, 7 Keble Road, Oxford, OX1 3QG, UK, +44

(0) 1865 601613, or by e-mail at marina.jirotka@cs.ox.ac.uk who will do her best to answer your query. Alternatively, you may contact the research assistant of Marina Jirotka: Barbara Grimpe, Department of Computer Science, University of Oxford, Wolfson Building, Parks Road, Oxford, OX1 3QD, UK, +44 (0) 1865 610607, or by e-mail at barbara.grimpe@cs.ox.ac.uk. If you remain unhappy and wish to make a formal complaint, please contact the Research Ethics Committee at the University of Oxford at ethics@socsci.ox.ac.uk; +44 (0)1865 614871; Social Sciences & Humanities Inter-Divisional Research Ethics Committee, Oxford University, Hayes House, 75 George Street, Oxford, OX1 2BQ, UK.

Annex 2: interview schedules

Please note: in order to ensure anonymisation some words or phrases in the following schedules needed to be deleted. Also, the schedule for interview 3 has been omitted as it has been written in another language than English and would help identifying the related interviewee(s). The schedule for the focus group has been omitted for similar reasons: too many details allow for the identification of the focus group participants.

Schedule for interview 1

Responsibility (liability/blameworthiness; care; responsiveness; accountability)
Responsibility is a key concept in our GREAT project, and it has many meanings.

- How would you apply this term to your own work [in] SNIFFPHONE?
- And to the work of the consortium as a whole?

AG parameter product

- From your point of view, are there any (potential) ethical implications of the envisaged SNIFFPHONE technology?
- You have explicitly included an RRI approach in your project (see p. 12). Would you explain to me:
    - What do you have in mind? --- go through the different aspects mentioned...
    - Why did you decide to include this?

The 'ethical approach' sketched on p. 6 of the research proposal:

- Would you please elaborate on the key terms – autonomy, ...?
- What do you have in mind for this approach? What are you currently developing, or planning to develop?

See also p. 7+8 on this: a somewhat 'ethical' approach seems to be key to actually advancing in breath sensing technology to date;

- But there's the (doubtful) objective to allow for pre-cancer monitoring/management;
- possible inaccuracy;
- questioning of 'traditional' cancer experts' knowledge/treatment;
- abuse of data processed remotely

First-order reflexivity; AG parameters Tools, Process and Participatory Approach

- Are there any 'tools', mechanisms or other processes set up in the project for facilitating ethical reflexivity?
- And throughout the project? (responsiveness)
- Prompt: any ethical board/committee, ethical review process; comparable units/practices in place?
- A possible way of realising (ethical) reflexivity is to pursue a participatory approach – this includes both the internal stakeholders (consortium members) and external ones: future technology users ('lay' people, GPs, ...), but also indirect users, e.g. in SNIFFPHONE perhaps: public health care data analysts [?].
    - Have you engaged any of these various stakeholders, or plan to do so? If yes, how?

Participation and deliberation

- Have you already experienced potentially conflicting views on this project – within the consortium, or through external stakeholders of any sort?
- If yes, what do you do with these – how do you go about them (within the project ... or somehow outside...?)?

Responsiveness (also: second-order responsiveness... overlaps with second-order reflexivity)

- Considering your first ideas/drafts of the research proposal some time before the final version: Did they look any different? Have you changed them in any way – if yes, how, and for what reasons?
- Would you please elaborate on:
    - how you understood the call of the European Commission;
    - whether and how you shaped the proposal accordingly;
    - any exchange of information with/ feedback from the EC about your envisaged project – at all stages of your preparation, Kick-off, the first months etc.
    - Has the EC raised any issues? If yes, how did you respond to these?
    - Any of these issues to be considered 'ethical'? If yes, how did you respond to these?

Second-order reflexivity

You may have already had various meetings, and exchanged many ideas, before and during the project, with the EC and all kinds of other individuals/organisations.

- Have you ever changed your mind about the project after such meetings/exchanges of ideas?
- If yes, in which way?

Did this change of mind lead to a change in the approach? If yes, how?

Schedule for interview 2

- Please explain your role/tasks in this project

- Please report on any important points in the preparation of the proposal, and in consortium discussions [...]

Ethical or RRI issues in the project

- Have you surfaced any relevant (future) ethical or RRI issues so far – for the envisaged product/outcome, for the project as a whole --- before the project (*anticipation*), or later?

- Have these already been addressed at the consortium level (or do you plan to address them)? If yes, how?

- *Responsiveness*: have you already noticed (or even initiated) any important changes in the project?

AG parameter Participatory Approach, Governance Model (Consultation?)

- *'Internal'/'external' stakeholder engagement*: Who designed questionnaire and interview schedule?
  (... clinical experts needed; perhaps also regulators in telemedicine)

- *External stakeholder engagement*: Who do you invite to respond to questionnaires, and to be interviewed? (consider also: end-users/patients; reps of patient organisations; reps of regulatory agencies)
- Any pre-study/pilot study with survey and interviews? Or: interviews serve as pre-study?

- *Ethical governance --- towards co-construction, and responsiveness*:
  - What are the actual work steps of: data gathering, analysis, ...?
  - Any feedback into the design process? When, how? Repeatedly?
  - Any option for radical dismissing of SNIFFPHONE idea?
  - Introduce this possible scenario to consortium?
  - (Anticipation: any 'enabling spaces' for user-oriented bottom up approach – with end-user/patients and end-user/clinicians --- and perhaps also other actors (see above)?

- Raising awareness of potential biases in selection of respondents/interviewees: how do you choose/have you chosen the participants? (*Field access; second-order reflexivity in terms of participants --- see workshop finding: usually respondents/interviewees are preselected by industry...*)

Nanotechnology and ethics

- Shouldn't you/we also address any ethical issues particularly related to nanotechnology? (E.g. H. Sutcliffe's work) --- Or have you already done this in any way? --- Broad (public) engagement early on in the project (cf. Pellé 2013)?
- Accordingly, perhaps also invite related stakeholders to interviews? (e.g. any nanotechnology initiatives/NGOs?) --- or plan another type of event/'RRI exercise' – as soon as possible? (*see 'enabling spaces'/anticipation point mentioned previously*)

Second-order reflexivity

- We need to surface the rationales/world views/presuppositions, and any vested interests between:
  - The four different scenarios
  - Population-based screening of all individuals, or groups, ...

... from various perspectives:

- public health (policy, economics) --- perhaps with pronounced interest in low national costs?
- GPs, clinical experts --- with a (more) individual-centred perspective --- but also other interests?
- ICT companies --- see EC call: EC wants to improve industry's competitiveness!
- Others?

... how may these different perspectives shape (or already have shaped) the project explicitly or implicitly? Willingly and unwillingly?

AG parameter cultural differences

- *See my remarks in questionnaire, p. 3; and interview schedule p. 1*

A 'black-boxing' of the envisaged technology is noticeable

- *See my remarks in both questionnaire and interview schedule*
- Desired, intended? If yes, why?
- Or unavoidable as
    - The project participants are not yet sure about the intended features --- if yes, because they are contested, or because it's not possible, ...? (possibly Collingridge dilemma at play here)
    - the technology only (co-)evolves with:
        - with development/'progress' made in certain WPs?
        - what you (vaguely) surface, and perhaps iteratively try to specify further, through the user-centred approach in WP [...]? and/or in your exchange with other WPs?