# Responsible Innovation Lab Report & Roadmaps

## D2.4 Report 3: Biomedicine (ES)

RESPONSIBLE INNOVATION COMPASS

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# 1. Lab Report

The interviews and workshops undertaken as part of the COMPASS (710543) project elicited useful and often insightful comments about the role of technologies and how both 'technology push' (with vested interests among some manufacturers and suppliers of healthcare technologies 'comfortable' within the present, more institutional, healthcare context) and 'consumer pull' factors (with more and more people seeking to access health services in new ways, using the technologies that are increasingly available to them) were influencing the sector. This report discusses the methodology and provides a short analysis of the key factors in the

## 1.1. Methodology

Interviews (as part of Work Package 1) were undertaken with 18 senior staff in healthcare technology companies (5 in the United Kingdom, 4 in Austria, 3 in Cyprus, 2 in Spain and 1 in Slovenia). Two Responsible Innovation Lab workshops were held in Spain, the first introductory online session with two further face to face meetings with staff each from different biotechnology companies 'concerned with products or services aimed at improving the wellbeing of people, often in the context of specific diseases'. This report detailing the development of the roadmap for biomedicine necessarily includes the integration of the results from the interviews, as the workshops themselves only produced information at a relatively superficial level (this will be further explored in the comparative assessment report, D2.5, with recommendations based on these results given in the final method kit, D2.6). It was necessary to incorporate results from the interviews to help to contextualise and build on information given in the lab workshops by the participants so that the roadmap could be successfully developed.

Most of the companies (both interviewees and workshop participants) were relatively small and, whilst they had concerns (as would be true of any commercial organisation) about 'getting to market' and making a profit, a clear ethical dimension was in evidence. The companies were, after all, in the business of researching and designing technologies or services to people who were often living with different health conditions.[1] Interestingly, with the companies involved, most of the manufacturing and supplying of the products was outsourced.

The interviews and workshops were presaged by work to recruit participants. There were some non-responses from companies approached which we believe was, in the main, due to sensitivities about commercial confidentiality. Added to this may be time considerations and a reluctance of the companies in question to subject themselves to what they may have seen as over-intrusive enquiry. This means that neither the interviews nor the workshops can be considered as necessarily representative. They do, however, give a good indication of current concerns and issues that are highly relevant to our mission to explore the extent to which 'responsible innovation' is being practiced and the barriers for its further development.

[1] In some cases these people (patients) in third world countries; many were frail or lived with long-term conditions sometimes supplemented by physical and sensory impairments.

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The interviews and workshops guided participants in relation to key ethical issues that relate to 'responsible innovation' but then, through raising non-leading questions, they invited responses and, through further probing (not prompting) gathering a richness of information that helps inform the content of the roadmap (see later).

## 1.2. Analysis

With regard to the outcome of the interviews and lab workshops it was striking the extent to which there was an embedded sense of responsibility in place. Linked with this was a positive regard for codes of practice, regulations, standards or, rather (as noted below) the right 'kinds' of regulation that was seen as underpinning good governance. Verbatim comments are dove-tailed into the text help to illustrate the findings both with regard to more generic aspects of 'responsibility' and some of the specific elements of RRI.

> ***I think if you are not a total capitalist, responsibility for society is a mandatory thing to do. Especially if you have employees, if you have kids … it's self-explanatory that this should be. (Participant)***

> ***Applying RRI is not a matter of decision - it's a matter of culture. You have to be responsible … it's called procedures, approvals or whatever. So [for] companies in this domain, this is the only way forward. (Participant)***

> ***In some respects [health care innovation] is by definition socially responsible – so if somebody is trying to develop a new MRI it's not like they're only doing it for money. They have their goal to serve patients. (Participant)***

> ***We have our processes in place which qualify us to be a medical device manufacturer. We have an internal code of conduct which addresses openness, fairness but also the willingness to accept change. (Participant)***

> ***Because medical devices go from implantable heart rate sensors to external pregnancy tests … you have to make these things work properly. (Participant)***

We can note the same sense of responsibility (accompanied by a regard for regulation) was found by Auer and Jarmai (2018) in their interviews with Chief Executive Officers of eight Austrian companies 'developing innovative medical devices'.[2] They list, based on their findings, a set of 'drivers for and barriers to innovation' as follows (see Table 1) – noting for almost all of these 'factors' (the exception is 'market orientation') that aspects can be positive (i.e. as drivers) or negative (as barriers). Regulations (noted further below), whilst generally accepted and valued were, however, seen as a double-edged sword. Auer and Jarmai affirmed that 'the regulatory framework is considered not only to drive innovation but also to cause delays in the company's research and innovation processes'.[3]

| Factor | Comment |
|---|---|
| **Regulatory Framework** | Recognising the role and purpose of standards and enabling certification to be obtained if and when appropriate. Some regulations (including standards) where seen as restrictive. |

[2] Auer and Jarmai (2018) op cit.
[3] Ibid.

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| | |
|---|---|
| **Funding and Finance** | Impacting on the sustainability of companies and their ability to invest in innovative ideas. Significant concerns about access to and availability to funding. |
| **Market Orientation** | Understanding markets and attuning companies activities to market needs. Relates to links with customers (and external knowledge, noted below). |
| **Customer Knowledge** | Obtaining feedback from, consulting with and involving customers in the innovation process. Uncertainty in some instances of the added value of the same. |
| **Management and Organisational Structures** | Recognising their contribution to good governance and facilitating innovation. Concerns, especially for the smallest companies, regarding the necessary time and resources to put in place effectively. |
| **External Knowledge from Collaborators and Networks** | Recognising the benefits of networking to obtain expert knowledge that contributes to innovation (and market understandings). Seen as potentially compensating for lack of internal resource. |

*Table 1: Drivers and Barriers to Innovation (per Auer and Jarmai)*

Looking generally at the elements of RRI (and setting aside the 'umbrella' elements of governance and ethics) the interviews and workshops found high consciousness of several of these, though not under the RRI rubric. This is to be expected given the 'novelty' of RRI. Auer and Jarmai (2018), in fact, found that none of their eight interviewees (in this sector) were aware of RRI. All, however, reported clear ethical practices within their companies with Auer and Jarmai observing 'that the representatives of our group of Austrian medical devices SMEs are aware of responsibility issues and are, in general, interested in increasing their company's positive impact on them'.[4]

> ***We want to publish … but actually I have competition. They are technical and more equipped [and] have more manpower so they can advance in this area. So [my] company does not share everything. (Participant)***

> ***If competitors don't follow responsible research and innovation but we in the company [do] it could be to our disadvantage. (Participant)***

> ***You've got to accept that you may be more expensive than your competitor because, actually, he doesn't care at all. (Participant)***

In raising questions about specific RRI elements in the interviews and workshops, positive views were generally expressed – though frequently these were countered by references to the commercial realities that they faced. A high level of openness was seen, therefore, a luxury that could not be afforded given its potential consequences in terms of loss 'innovative ideas' to competitors, with consequential loss of competitive advantage (and *ipso facto* of potential profits that can be obtained by being early to market with a particular innovation). Having said this some degree of involvement of patients (people) and customer feedback was certainly seen as important.

[4] Auer and Jarmai (2018) op cit.

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Such feedback (and the direct experience of providing services using healthcare technologies) also meant awareness of the importance of the technologies and services being available to the widest number of people. Indeed, there was, for some (though not widely explored in the interviews and workshops), a sense in which the technologies were of limited value *unless* available in the sense indicated.

> ***Then, of course, you have to do post market surveillance, meaning that if there is a complaint from a customer you always have to decide 'Do I have to report this? Do I have to make a call back of products?' and so on. (Participant)***

> ***It's possible to get really good treatments nowadays but they are becoming so expensive in a world where the gap between the poor and the rich is continually increasing. Even if you make a lot of progress and you are novel, if they [your products] they are not accessible to everyone – well, they are useless. (Participant)***

Having said this, many were aware that openness in the sense of engaging and involving different stakeholders (including patients) could have commercial advantages.

> ***So how do you mitigate between [a] cheaper product according to [a] very demanding timeline and, at the same time making sure that you give the opportunity to everyone to get to be involved? We need to think in economic terms [but] also look at the benefits … are we improving access? … are we cutting out unnecessary health risks? … are we exposing patients by them going into [health] facilities when they don't need to? (Participant)***

> ***Because of the economic pressure and the challenge of introducing innovation, I think my concern is that a lot of players are not paying enough attention to the patient … what the patient needs. (Participant)***

> ***If you leave some people out, it will bite you. It will halt adoption [of the product] and your success. (Participant)***

Science Education was not a clear concern. There appears to have been staff pressures but, for most, adequate momentum behind innovative activity. Rather the main concern was in getting to market, especially when the major health technology purchasers (e.g. hospitals) presented various hurdles. There was concern, furthermore, that some healthcare service providers were looking to their own needs (around diagnosis and treatment) but in some contexts were not responsive to patient views. Innovation, we have noted above, is taking place both in the institutional and wider community contexts.

> ***The physician wants a good diagnostic result and the patient wants to be treated in the optimum way. And those are often conflicting interests. (Participant)***

> ***Today I'd say the hospital is the only decision-maker at the end of the day. The physician can make pressure [if] the product is good … sorry for saying this but the interest of the patients is a very small lobby in this situation. (Participant)***

There appeared to be a general readiness to employ and engage both men and women at all levels within the companies, this perhaps reflecting that overall ethical perspective within which patient needs, regardless, of gender required to be met. Health technologies may, therefore, be seen as serving the needs of all - with the evident ethical orientation (around gender equality) being reflected in the work of the companies.

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And finally, because of the 'defined' nature of the RRI elements, environmental stewardship was not raised in the interviews or workshops. It remains, however, an ethical consideration that requires, it is suggested, greater consideration in the context of health technologies and services – especially for the technologies and services that characterise telehealth where there are significant implications for travel (for staff and patients). Better health management, furthermore, can lead to reductions in polypharmacy (with all the associated production, delivery and wastage costs).

The outcomes of the interviews and workshops can only be regarded as indicative but these, and the verbatim comments, are helpful as we move forward to set out a roadmap for the sector. 'Responsibility' is, it became clear (because of the already ethical orientation of the companies), already largely in place and could be built on more easily than is the case for other sectors. Moves towards further 'responsible innovation', however, necessitates attention to some areas of (potentially dramatic) change, at least for some companies within the sector, as highlighted in the 'Features' noted earlier in this report. Such attention calls, most notably, for greater understandings of the implications of changing markets and new service frameworks – that respond more to the consumer 'pull' and are more ready to set aside 'technology 'push'.

# 2. Roadmap Introduction

This roadmap helps to shape ethical approaches to innovation within the healthcare technology and services sector. The work draws on relevant published information and follows consultations undertaken through interviews and workshops with a sample of healthcare (including biomedical) companies.

The context for the roadmap is set through an introductory section that focuses, most notably, on Corporate Social Responsibility (CSR) and the way that this relatively well known aspect of commercial conduct links to Responsible Research and Innovation (RRI). What follows are then pointers to three 'features' that most strongly characterise the sector. First is the 'mediated market' recognising that healthcare technologies and services are often embedded within institutions that have particular procedures and protocols that determine their use or their configuration. Second is the ethical imperative that relates to the activities of commercial organisations and for whom profits must be seen in a context that relates, ultimately, to people's care and/or well-being. Third is the rapid development of technologies and the impact that this is having (or promises to have) in relation to design and accessibility for both institutions and consumers (patients) – this, in turn, impacting on the very nature of services that are underpinned by the technologies in question.

The exploration of these three features draws from both the published information and the consultations. The feature concerned with advancing technologies was particularly highlighted in the consultations. This was linked to commercial aspirations that were often focused on the institutions (representing the 'mediated market') – these being (correctly) seen as, in many cases, being sustained through public funding and as potentially expanding in their role due to our changing demographics and public health challenges. An awakening was, however, apparent, in relation to market changes – with a growing orientation towards individuals (users, consumers, patients) who would increasingly be taking responsibility for their own lifestyles and health behaviours (albeit often in partnership with clinicians and others).

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Finally a roadmap for the healthcare technology and services (biomedicine) sector is set out. This points to some fundamentals considered as vital for companies (or, indeed, any enterprise) involved in the sector. Some of these carry little surprise in invoking the need for initiatives to be well evidenced. What is also emphasised, however, is the need for such initiatives to take greater account of user (patient) perspectives. This, of course, relates to the ethical imperative noted above and also to recognition of the need to afford greater choice for people in managing their health (and their accessing the technologies to help them to do this). Such issues are noted as impacting on the designs of products ('safe by design' is noted as important) but also on service configurations whereby users (patients) are empowered.

It follows that the roadmap requires that companies should have and implement appropriate codes of practice (understood and practiced by all staff) that help to embed an appropriate service ethos – and that related technologies are designed to support this. Associated with this is the necessity of (a) a heightened readiness among companies to respond to the changing demographic and public health agendas; and (b) maintaining links with users (patients and/or healthcare professionals) so that they are sensitised to their needs and aspirations. Both of these link, of course, with the notion of 'responsibility' within 'responsible innovation' and *ipso facto* with RRI.

# 3. Roadmap Contextualisation

The COMPASS (710543) project commenced in mid 2016. It is funded by the European Commission under the GARRI programme on Responsible Research and Innovation (RRI). The European Commission definition of RRI is as 'an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation'.[5]

The COMPASS (710543) project objectives were concerned to provide evidence of and promote 'better uptake' of RRI in three key sectors of innovation, each of which was seen as linking to particular societal challenges (or threats, see Table 1 'Sectors in Focus'). These areas are healthcare technologies and services, nanotechnology and cybersecurity.

| Sector | Challenges |
|---|---|
| Healthcare technologies and services (biomedicine) | Maintaining health and wellbeing in a context of demographic change; empowering service users through technologies and service design; promoting greater health literacy and facilitating self-management of health. |
| Nanotechnology | Avoiding damage to the environment; promoting better air and water quality; ensuring safety when seeking to realise the potential of new products (e.g. for coatings and precision medicine); avoiding the danger to people of ingesting nano-particles. |

[5] See https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

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| | |
|---|---|
| Cybersecurity | Protecting individuals, businesses and services against cyber-threats and their consequences in terms of service breakdowns, disruption to manufacturing and distribution systems, financial and reputational loss, identity theft, fake news, etc. |

*Table 2: Sectors in Focus*

In this roadmap we concentrate on **Biomedicine** (more specifically in healthcare technologies and services, as it may hence be termed hereafter). There are, however, some common aspects of RRI that apply in each sector.

The work of the COMPASS (710543) project has been informed by both primary and secondary research. It draws on multiple sources (some of which are noted in this report); the undertaking overall, in total, of nearly 30 personal interviews with senior staff in the three sectors; and the holding of successive workshops (to identify issues and inform the roadmap) with staff at different levels. The latter have involved some 15 organisations.[6]

In the course of identifying both individuals and companies to engage with the project, it became clear, at that initial point, that their awareness of 'Responsible Research and Innovation' was low.[7] The simpler term 'responsible innovation' was, therefore, quickly adopted by the project and is used throughout this report (except where a specific facet of RRI is being discussed or quoted).

The project will, in 2019, complete its work by testing and revising roadmaps for the three sectors. Educational and training materials, together with a self-test tool will be provided. These materials will help organisations in those sectors (whether in public ownership, for profit or not for profit), to consider in depth some specific ethical and governance issues that impact (or will impact) on them as they pursue sustainable commercial goals.

*What is 'Responsible Innovation'?*

The idea of responsible innovation is not new. One researcher references the invention of a flying machine, known as the Passarola ('ugly bird'), designed by a Portuguese priest (Bartolomeu Lourenço de Gusmão) around 1700 (see illustration below). A 'rudimentary'

[6] Detail of the methodology is posted on the project website at www.innovation-compass.eu .

[7] That levels of awareness are low is unsurprising. This does not detract, however, from a significant level of public interest in scientific matters as is evidenced in a Eurobarometer survey undertaken in 2013. Eight out of ten respondents agreed that the 'EU should actively promote worldwide respect for European ethical principles for conducting scientific research'. See European Commission (2013) 'Eurobarometer Responsible Research and Innovation, Science and Technology', Memo 13,987 Brussels.

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version was launched in 1708.[8] The inventor, surely an innovator (albeit that written accounts are scant),[9] reported its potential benefits in terms of transport and also its use in war.[10]

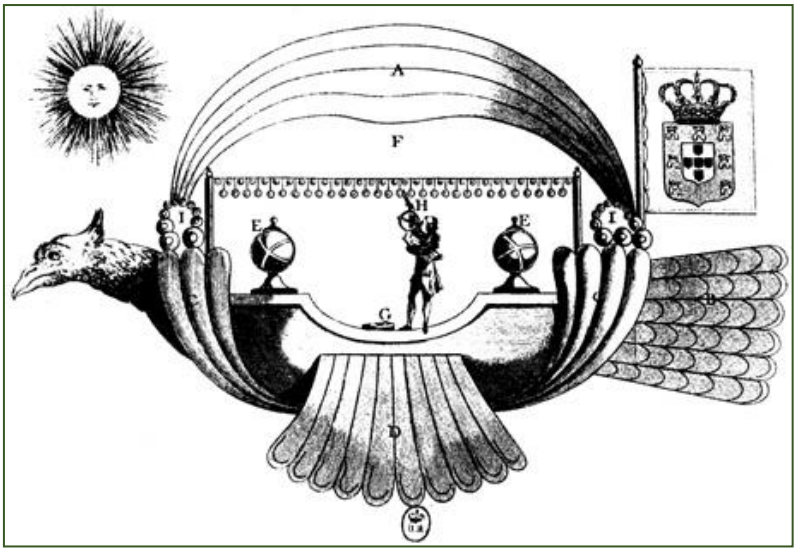


*Figure 1: The Passarola (Ugly Bird)*

The important point here is that there was a consciousness at that time that, whilst technologies are in some senses neutral, they might be used for good or ill. It was a matter of 'responsibility', therefore, to consider the uses to which they might be put – and if necessary to place restrictions on their availability.

It is highly unlikely that the European Commission had the dilemmas associated with the 'ugly bird' in mind when conceiving of RRI. The Commission would, however, have been influenced by debates and discussions that addressed (in modern parlance and in relation to contemporary innovation) the tension between the benefits and any negative potential effects of emerging technologies.

In the 300 years since the 'innovative' idea of the 'ugly bird' was put forward, the debates and discussions have continued as technological developments take place and their positive and negative effects have been evident – from industrial reform (characterised by increased productivity and the loss of jobs through mechanisation) to warfare (characterised by increased suffering and loss of life). And it is in the context of war that we can note two major contributions to the debate, those of Robert K. Merton, a sociologist, and Karl Popper, a philosopher (see Fig 2).[11]

Merton, in 1942, affirmed that 'scientists have been jarred into a state of acute self-consciousness: consciousness of self as an integral element of society with corresponding

[8] See translator's note in Saramago J (1982) 'Baltasar and Blimunda', Random House, London.
[9] Videira Louro F and De Sousa JM (2014) 'Father Bartholomeu Lourenço de Gusmão: a Charlatan or the First Practical Pioneer of Aeronautics in History', Paper to the 52nd Aerospace Sciences Meeting, National Harbour, Maryland.
[10] Von Schomberg R (2013) 'A Vision of Responsible Innovation' in: Owen R, Heintz M and Bessant J (Eds.) 'Responsible Innovation' London: John Wiley pp51-74.
[11] Work by other theorists is noteworthy - see, for instance, Polanyi K (2001) 'The Great Transformation: the Political and Economic Origins of Our Time', Beacon Press, Boston. Polanyi's book was originally published in 1944.

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obligations and interests'.[12] He railed against a 'sanguine isolationism' whereby 'he' [sic, the scientist] might have come to 'regard himself as independent of society'. Merton offered five methodological canons which have (and retain) relevance to 'responsible innovation'. These included an 'ethos of science' that demands improved knowledge and the maintaining of a moral COMPASS (710543); 'disinterestedness' in order to remove judgements that may be biased; and 'organised skepticism' so that questions of fact' may be asked about the 'potentialities concerning every aspect of nature and society'.

Karl Popper's work can be seen as complementing that of Robert K Merton. Popper held that 'scientific practice is characterized by its continual effort to test theories against experience and make revisions based on the outcomes of these tests'.[13] *Within that practice Popper recognised two kinds of scientific 'boldness' – first, relating to scientists making testable claims with a 'willingness to take a risk of being wrong'; second, having* the 'readiness to look for tests and refutations'.

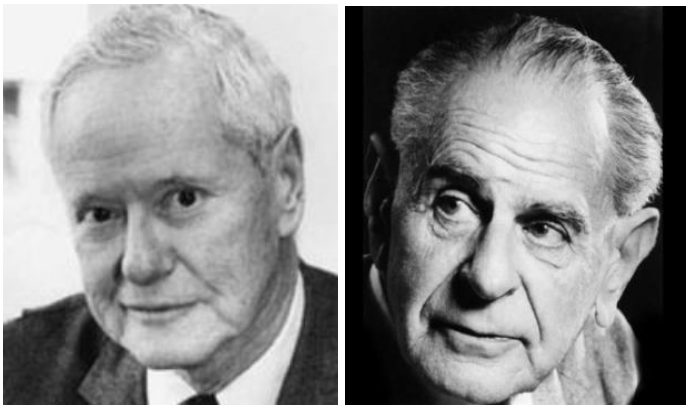

*Figure 2: Robert K Merton (1910-2003) and Karl Popper (1902-1994)*

The asking of questions (Popper) and the testing of theories (Merton) both resonate with the notion of 'reflexivity' – a key element of RRI. Such reflexivity has been defined as 'the process by which experience and knowledge continually influences attitudes, behaviours and actions and *vice versa*. This may be 'first order' relating to particular knowledge for a time or event; or 'second order' relating to new knowledge and understanding'.[14] It is illustrated in Fig 3.[15]

[12] Merton RK (1942) 'Science and Technology in a Democratic Order', Journal of Legal and Political Sociology 1 pp115-126.
[13] Shea B (2016) 'Karl Popper, Philosophy of Science' in Fieser J and Dowden B (Eds) Internet Encyclopedia of Philosophy. http://www.iep.utm.edu/pop-sci/
[14] Wilford S, Fisk M and Stahl B (2016) 'Guidelines for Responsible Research and Innovation', Centre for Computing and Social Responsibility, De Montfort University, Leicester.
[15] Gianni R and Goujon P (2013) 'Analytical Grid: Current Theory and Practice (in RRI)' GREAT Project.

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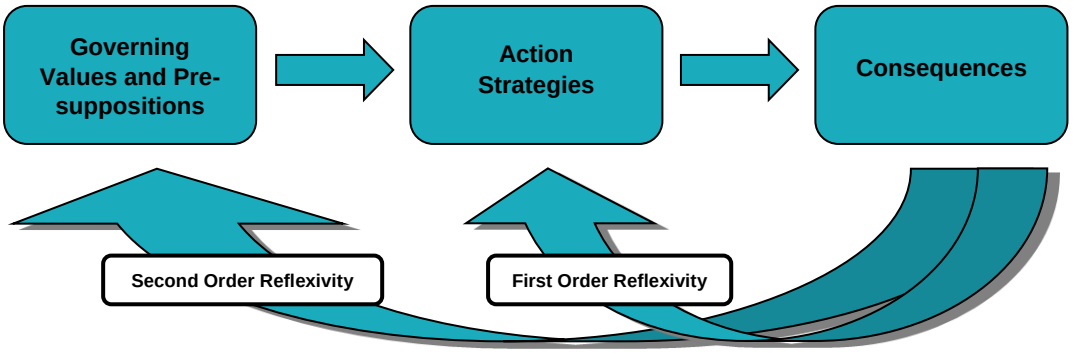


*Figure 3: Reflexivity (per Gianni and Goujon)*

*Themes and Issues*

The introductory discussion points to the emergence of some key aspects of responsible innovation. These relate to matters such as risk, openness and the importance of scepticism. Responsible innovation, it follows, is doing things in ethically appropriate ways in order to ensure that 'social as well as commercial benefits are harnessed; and that any harm to the social and physical environment is obviated or minimised'.[16] Reflexivity can be noted as one of the key mechanisms by which 'responsibility' can be exercised. For the purpose of this roadmap the definition of 'innovation' is set aside in deference to those who have particular expertise in the specific sectors where it is deemed to take place.

The backdrop to this roadmap is, therefore, at least partly in place. The task now is to consider such matters in relation to contemporary thinking and, crucially, to set out, in a 'roadmap', what this means for companies (corporately) and researchers (individually) in pursuit of 'responsible' innovation.

The context is one where the intense pace of technological developments must be recognised. These relate, almost needless to say, to innovation around (amongst other things) communications technologies (with the advent of the Internet) and to developments that are evident in all three areas that are the focus of the COMPASS (710543) Project (healthcare technologies and services, nanotechnology and cybersecurity). None of these developments will have been in the minds of Merton or Popper (and certainly not de Gusmão). But there are two contemporary perspectives that are familiar to many industrialists, researchers and entrepreneurs. Both have ethical dimensions that can be seen as responding to the ongoing imperative concerned with harnessing benefits (doing good) and avoiding harm. These perspectives are those of Corporate Social Responsibility (CSR) and Constructive Technology Assessment (CTA).

The notion of Corporate Social Responsibility (CSR), of course, relates to centuries old debates about responsibility in industry. The specific 'label' of CSR, as noted by Madrakhimova (2013), is one of many that relate to corporate citizenship, responsible investment' etc., and is generally attributed to Howard Bowen who published a seminal work

[16] This draws from the definition of RRI provided in the GREAT project. See Wilford S, Fisk M and Stahl B (2016) 'Guidelines for Responsible Research and Innovation', Centre for Computing and Social Responsibility, De Montfort University, Leicester.

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'Social Responsibility of a Businessman' in 1953.[17,18] Crowther and Martinez noted CSR as being 'in vogue' in 2004 but opined that 'as a concept it [CSR] is vague and means different things to different people'.[19] That 'vagueness' extends, according to Pellé and Reber (2015) to the 'very definition of responsibility'.[20] The European Commission definition (though dating from 2001) of CSR is as 'a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis'.[21] The Commission also developed the schema of RRI but with it being 'unexpected' (according to Pellé and Reber) that its relationship with CSR had 'rarely' been addressed.

But CSR, according to Schroeder and Iatridis (2016), was the 'biggest and possibly most powerful concept' with a close link to RRI (and, by extension, to responsible innovation).[22] They affirmed the importance of three corporate responsibilities that relate to social, economic and environmental concerns – with CSR seeking to address the whole 'cycle of business life'. Of significance is that they noted were three issues that carry a healthy dose of reflexivity, viz.[23]

- the identification (and understanding of the significance) of social and environmental impact of business practices;
- exploring the efficacy of tools and policies to mitigate negative impacts (and the adoption of practices that 'look ahead' in order to effect their avoidance); and
- understanding, prioritising and addressing the concerns of the 'most important stakeholders', including customers.

Martinuzzi et al (2018) pointed to RRI 'building on and going beyond CSR' - expanding 'on concepts and theoretical approaches previously used'.[24] RRI, they argued (unlike CSR), seeks to embed 'responsibility' at 'very early stages of research and innovation' and carry the potential (albeit half a century after Merton and Popper posited their arguments) that 'RRI offers the potential to bring CSR from the margins into core strategic decision processes'.[25] Pellé and Reber (2015), meanwhile, had asserted that the 'CSR framework already provides a basis to develop the conception of responsibility in innovation'.[26] The question arises (albeit

[17] Madrakhimova FS (2013) 'Evolution of the Concept and Definition of Corporate Social Responsibility', Global Conference on Business and Finance: Proceedings 8,2 pp113-118.
[18] Pellé S and Reber B (2015) 'Responsible Innovation in the Light of Moral Responsibility', Journal on Chain and Network Science 15,2 pp107-117.
[19] Crowther D and Martinez EO (2004) 'Corporate Social responsibility: History and Principles' in Crowther D and Caliyurt KT (Eds) 'Social Responsibility World', Ansted University Press, Penang.
[20] Pellé S and Reber B (2015) op cit.
[21] European Commission (2011) 'A Renewed EU Strategy 2011-14 for Corporate Social Responsibility', Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM/2011/0681 final.
[22] Schroeder D., Iatridis K. (2016) The Basics of Responsible Research and Innovation. In: Responsible Research and Innovation in Industry. Springer Briefs in Research and Innovation Governance. Springer, Cham
[23] Schroeder and Iatridis (2016) op cit.
[24] Martinuzzi A, Blok V, Brem A, Stahl B and Schönheer N (2018) 'Responsible Research and Innovation in Industry – Challenges, Insights and Perspectives', Sustainability 10, 702 DOI 10.3390/su10030702.
[25] Martinuzzi et al (2018) op cit.
[26] Pellé and Reber (2015) op cit.

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not asked in this way) as to why RRI, with its particular construction, was needed when CSR is already in place and widely recognised?

Constructive Technology Assessment (CTA) is a concept that relates to socio-technical scenarios. It is supportive of and pre-dates RRI in its advocacy of stakeholder involvement. A strong advocate of CTA is Arie Rip who pointed, with Robinson (2013), to the provenance of CTA in the late 1980s in The Netherlands.[27] Two key components of CTA activity were noted as, first, 'the building of socio-technical scenarios of possible developments'; and, second, 'organizing the orchestration of workshops with a broad variety of stakeholders'. Both of these help the development of insights and knowledge by which better (or, rather, aware) and more reflexive decisions regarding technological developments can be made. Konrad et al (2017) explained that such stakeholder workshops 'typically start with the analysis of current and recent developments and then expand into the future, exploring different directions [and] how the observed dynamics may further unfold … also, how strategic and governance actions may play out and interrelate, or how different actor groups may react'.[28]

Rip and Robinson placed CTA within the broader context of technology assessments (TA) with an aim that was concerned to 'reduce the (human) costs of learning by trial and error … by anticipating future developments and their impacts, and by accommodating these insights in decision making and implementation'.[29] The adoption of CTA in any case was seen by them as increasing 'reflexivity' with a contribution to this being made through the involvement of a wider range of stakeholders.

Both CSR and CTA are therefore of some significance in helping to set a background within which we can consider 'responsible innovation'. A reference is necessary, however, to the thematic elements of RRI framework set out by the European Commission. It is arguable that, whilst of certain relevance, the framework is undermined by the remarkable exclusion of environmental concerns. Various studies have noted this, with Wilford et al (2016) simply adding 'Environmental Stewardship' (Taking Care of our Planet) to the European Commission list - set out in Table 3.[30] Ethics and Governance can, of course, be seen as something of a 'catch all' within which other ethical considerations (elements) are also brought into play.

*European Commission Thematic Elements of RRI*

| | |
|---|---|
| *Public Engagement* | Choose Together |
| *Gender Equality* | Unlock the Full Potential |

[27] Rip A and Robinson DKR (2013) 'Constructive Technology Assessment and the Methodology of Insertion' in Doorn N, Schuurbiers D, van de Poel I and Gorman ME (Eds) 'Early Engagement and New Technologies: Opening Up the Laboratory', Philosophy of Engineering and Technology 16 DOI 10.1007/978-94-007-7844-3 3. Springer Science and Business, Dordrecht. Note that Arie Rip has been consulted during the work of the COMPASS (710543) project.
[28] Konrad K, Rip A and Greiving VS (2017) 'Constructive Technology Assessment – STS for and with Technology Actors' European Association for the Study of Science and Technology (EASST) Review 36,3 November.
[29] Rip and Robinson (2013) op cit.
[30] Wilford et al (2016) op cit. See www.great-project.eu . For other studies see Martinuzzi et al (2018) op cit.; and Jirotka M, Grimpe B, Stahl B, Eden G and Hartswood M (2017) 'Responsible Research and Information in the Digital Age' Communications of the ACM DOI 10.1145/3064940.

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| | |
|---|---|
| *Science Education* | Creative Learning, Fresh Ideas |
| *Open Access* | Share Results to Advance |
| *Ethics* | Doing the Right 'Think' and do it Right |
| *Governance* | Design Science with and For Society |
| *AND ADDED (BELOW) IN THE GUIDELINES PRODUCED BY THE GREAT PROJECT* | |
| *Environmental Stewardship* | Taking Care of our Planet |

*Table 3: RRI Elements (per the European Commission)*

The above provides us with the context for this roadmap. It provides a number of reference points – with a background provided by Merton and Popper (and de Gusmão); and a more contemporary perspectives by Corporate Social Responsibility, Constructive Technology Assessment and the framework provided by the European Commission.

# 4. Specific challenges for Biomedicine

This exploration of challenges for biomedicine draws on secondary sources as well as the outcomes of direct work with a variety of healthcare companies in interviews and workshops with key staff. All were involved in the research, development and/or provision of healthcare technologies and/or services (biomedicine). Initially, in setting the context for such technologies and services it is important to recognise four major features of the 'sector'.

The first is the nature of the 'market' for health *technologies*. This is, in large part, mediated by institutions that provide health care *services* to those who (for other, non-health, technologies) would often be customers making open purchasing decisions. By 'open' we mean neither normally influenced by restrictions in supply (e.g. where a technology or service is proffered by a health institution or clinician in the public or third sectors), nor linked to an individual's health need.

The second relates to the preceding point, viz. that in being concerned with the health and wellbeing of individuals, there is a shared ethical imperative that relates to health technologies and services with this being, for instance, explicit in the Hippocratic Oath.[31]

The third is that health care services in many European countries are in crisis. This means that some health technologies are seen as having a messianic role in supporting new ways of service 'delivery' or, conversely, the means by which people can both better self-manage in relation to their health (and lifestyles) and access health services in new ways.[32]

These features are evident in much published work and have emerged from the work undertaken within the COMPASS (710543) project.

[31] The equivalent for nurses is the 'Nightingale Pledge'.
[32] The term 'delivery' is not favoured in this report on account of the implied one directionality of the service provided – i.e. not readily allowing for people to be partners in (or to more fully manage) their care.

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Feature 1: The Mediated Market

The mediated nature of much of the healthcare 'market' clearly distinguishes it from markets for other products and services. The view of technologies maintained by provider organisations (whether in the public, private or third sectors) is seen, in the main, through a lens of 'care'. Commercial objectives in providing health*care* are normally, therefore, mitigated because of that view – this being especially the case for those benefiting from public or third sector funding.

The introduction and use of healthcare technologies are generally subject to processes of procurement that may be restricted to known and trusted products. Procurement will often be concerned to maintain the *status quo* in terms of operational procedures and protocols and may be antithetical to the use of innovative technologies. There can, therefore, be resistance to the procurement and utilisation of newer technologies even though may be evidence of their efficacy. Linked with this is the paradox, as noted by Cristensen et al (2009), that technologies can be enablers that help e.g. in the development of precision medicine and the better targeting of treatments and therapies; and they can be disrupters that because their increasing pervasiveness and lower cost opens up part of the world of medicine to a wider public.[33] In respect of the latter, Lynch and Fisk (2017) observed that the use of such technologies by people who are more ready to play a part in the management of their health has the effect of 'undermining the long-held hegemony of clinicians who saw themselves as having mastery over technologies in healthcare'.[34]

Feature 2: The Ethical Imperative

The second major feature of the sector is the focus on, indeed, the ethical imperative of 'care'. This can be linked in some ways to the widely adopted bioethical principles put forward by Beauchamp and Childress[35]. Their (four) principles included beneficence and non-maleficence i.e. doing good and (echoing the Hippocratic Oath) doing 'no harm'. Looking at applied ethics in eHealth, Whitehouse and Duquenoy[36] considered non-maleficence as relating to increasing the quality of healthcare and reducing its risk (hence quality and safety). Beneficence was seen as promoting wellbeing, increasing levels of safety (rather than just reducing risk) and protecting people.

'Care', meanwhile, we can see as a contested concept and arguably degraded where seen only as relating to tasks (whether personal or practical) undertaken *for* patients. Of note in this context is the work of Joan Tronto. She points to an 'ethics of care', at least for nurses, concerned with wider attentiveness, responsibility, competence and

[33] Cristensen CM, Grossmans JH and Hwang JH (2009) 'The Innovator's Prescription: A Disruptive Solution for Health Care' McGraw-Hill Education, New York.
[34] Lynch J and Fisk M (2017) 'mHealth, Trust and the Security of Personal Data' in Marston HR, Freeman S and Musselwhite C (Eds) 'Mobile eHealth', Springer, Cham pp237-250.
[35] Beauchamp T.L. and Childress J.F., (2001) Principles of Biomedical Ethics, 5th edition, New York: Oxford University Press
[36] Whitehouse D. and Duquenoy P., (2009) 'Applied ethics and eHealth: principles, identity, and RFID' in Matya V., Cvrcek D., Fischer-Huebner S., (eds) *The Future of Identity in the Information Society – Challenges for Privacy and Security*, FIDIS/IFIP Internet Security & Privacy Summer School 2008, Boston: Springer, pp. 44-57

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responsiveness of staff.[37] The key point is that care is at the heart of the work undertaken by nurses, doctors and other medical staff. That work frequently includes the use of (healthcare) technologies – but access to which (as noted above), at least in institutional settings, is not usually at the behest of the patient. Technologies are, therefore, generally the servants of clinicians and are only occasionally (in community contexts) the tools of patients and are utilised by them to provide or access care. The associated ethical imperative of care, therefore, makes its mark very emphatically in the world of healthcare technologies.

Relating to this and specifically developed in the context of RRI, are six priorities set out in a 2013 review undertaken by the Nuffield Council on Bioethics. These are reported on and discussed by Gardner and Williams (2015) and include responding to 'clearly identified need', working on the basis of 'robust evidence', 'continuous reflexive evaluation' and 'coordinated interdisciplinary action' – the (ethical) aim being to ensure that 'research and innovation in the healthcare sector is directed towards greatest need'.[38]

At the same time (and looking more closely at advances relating to biomedicine), the Oviedo Convention of 1999 still carries ethical relevance.[39] This affirms the need to preserve human dignity, rights and freedoms through 'a series of principles and prohibitions against misuse of biological and medical advances' covering medical research, consent, rights to private life. All forms of discrimination on the grounds of a person's genetic make up is outlawed and predictive genetic tests are only sanctioned for medical purposes.

Feature 3: Advancing Technologies and New Service Frameworks

When considering new service frameworks, again Cristensen et al (2009) is a good place to start.[40] But even they would have been taken aback by the rapid changes in people's use of (new) healthcare technologies - with their clear potential for disrupting established service frameworks. These rapid changes have taken place in the decade since they published their book. Note here the reference to 'people's use' - because our purview of healthcare technologies can no longer be one that relates narrowly to the hospital or clinic, but also must consider the people (rather than necessarily 'patient') perspective in the home, the workplace and more.

What were (and largely remain) somewhat centralised structures with predictable and well established procedure and practices are, in fact, under threat by a new raft of services supported by often innovative healthcare technologies that come under the umbrella term of 'digital health'. Linked with this is the increasing use of Artificial Intelligence (AI), robotics and 'precision medicine'.

At the core of digital health and biomedicine is the more effective use of data - and much of the innovation in this sector is concerned with the means of gathering such

[37] See Ash A. (2014) 'Safeguarding Older People from Abuse'. The Policy Press, Bristol.
[38] Gardner J and Williams C (2015) 'Responsible Research and Innovation: A Manifesto for Empirical Ethics?' Clinical Ethics 10,1-2) pp5-12.
[39] See https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

[40] Christensen et al (2009) op cit.

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data and using it in the cause of either more precision (in healthcare) being 'delivered' or the related monitoring of individual and (in the case of public health) community health and wellbeing.

Within arena of digital health, a strong focus in this report is on 'telemedicine'. With telemedicine in mind Cristensen et al saw the potential for an 'opening up' of medicine - with 'connected' clinicians being enabled to share images and health data in order to help them with decision-making.[41] They saw this same connectivity as enabling a 'virtual decentralisation' of services. But, as noted by Lynch and Fisk, they failed to extend the logic of their argument to points of care that were beyond the local clinic.[42]

It is now necessary, therefore, to think in terms of health decentralisation more widely and of its implications for the locus and usage of healthcare technologies. That decentralisation extends the locus to the person who can be enabled in accessing health services through mobile or worn devices as well as (potentially) being connected to health services through other devices when at home, at work or 'on the move'. This takes us in to the world of 'telehealth', defined by the Telehealth Quality Group as 'the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them irrespective of their location'.[43] Where these new kinds of links involve the potential to (from the patient's point of view) consult clinicians and healthcare practitioners online this provides a perspective on healthcare technologies that stretches in order to include devices from the ordinary telephone to video-links. It includes apps, the rapidly increasing use of which has been noted by Chambers et al (2016) as well as Lynch and Fisk (2016).[44]

These kinds of links involve the potential (from the clinician's point of view) to monitor people's wellbeing online (e.g. their activity and behaviours or physiological signs), this calling for non-traditional uses (and, therefore, configurations) of healthcare technologies – several of which bring particular ethical dilemmas in relation to such matters as privacy and consent. They involve (more from the people's or patient's point of view) the use of technologies that include those where software and/or new functionalities are embedded within generic devices (like the mobile phones or a smart 'home hubs') in order to ensure that healthcare is accessible through service menus (that can relate, of course, to a wide range of non-health services). This, and the role of new, potentially innovative, healthcare technologies, in facilitating communication *and* data collection, means that our purview must now consider (within our technological 'brief') both the technologies themselves and the software that determines the manner of their operation. It is, in other words, no longer a matter of medical machines that 'do' things, it is technologies within intelligent systems that can be used in ways that prop up the *status quo* or can facilitate the further emergence of new service frameworks. There is, therefore, the need to consider changing modes of

[41] Ibid. The idea that such data might be shared with and accessible to patients …
[42] Lynch and Fisk (2016) op cit.
[43] See www.telehealth.global It should be noted that definitions around telemedicine and telehealth are fluid. Other terms, notably telecare, can also be encountered. All these come under the umbrella term of 'digital health' or 'eHealth'.
[44] Chambers R, Schmid M and Birch-Jones J (2016) 'Digital Healthcare: The Essential Guide', Otmoor Publishing, Oxford.

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service management and the 'cultures' of care – at one end of which are dilemmas, noted by Cuijpers et al (2014), for the care of people with dementia where a high degree of monitoring (for 'care') is arguably justified.[45] At the other end is the ethical imperative around the empowerment of people to enable them to self-care.

Other linked innovative developments that cannot be ignored in this context include (the seemingly now multiplying capacity or call for) sensors in the home. These are sometimes embraced by the term 'Internet of Things' and can be seen as integral to idea of 'smart homes'. Some may come within what has been termed the Internet of Medical Things (IoMT).[46] In either case there is, of course, the challenge of connectivity and, very important in the world of healthcare, interoperability.

Other sensors that come into view are those which are worn or carried (such as embedded in fabrics or built into devices such as the Fitbit). The concern of all of these sensors is gather data of one sort or another by which, through analysis and interpretation greater understandings (of people's health and lifestyles) can be derived.

The importance of such developments cannot be readily overstated. Data, as noted by Loder and Nicholas (2018) in a report focusing on artificial intelligence (AI), has been called 'the new oil' and carries a commercial value.[47] And whilst there is clear potential in the area of healthcare, there are also crucial ethical and practical issues that need to be addressed, including those of privacy and confidentiality, also the ownership of personal data. if the patient (people) position is to be properly safeguarded.[48]

*A Note on Standards*

Standards have been touched on earlier in this report and referred to as a 'double-edged sword' by reference to somewhat ambivalent views about their merits. Kuhlmann et al (2016) have demonstrated a balanced approach to the issue by pointing (within a set of ten 'governance principles and requirements for responsibilisation') to the need for 'a careful combination of 'hard' and 'soft' regulatory mechanisms [that] … allows for self-regulation and organisation, as well as external control and accountability structures'.[49]

***There is the point about over-regulation. This is a way where responsibility is enforced in a counter productive manner … always more and more regulation, more rules to follow! (Participant)***

On the whole, however, the view about regulation (including standards) has been noted as favourable – these being seen as especially necessary in view of the vulnerability of end users (patients) of the technologies and services concerned. ISO 13485 was cited as the key

[45] Cuijpers YM, van Lente H, Boenink M and Moors EHM (2014) 'Quandaries of responsible Innovation: The Case of Alzheimer's Disease' in van den Hoven et al (Eds) 'Responsible Innovation 1 – Innovative Solutions for Global Issues', Springer Science and Busines Media, Dordrecht.
[46] See, for instance, https://www.technewsworld.com/story/83654.html
[47] Loder J and Nicholas L (2018) 'Confronting Dr Robot: Creating a People-Powered Future for AI in Health' Nesta Health Lab, London.
[48] The General Data Protection Regulation (GDPR) is very relevant here ADD INFO.
[49] Kuhlmann S, Edler J, Ordóñez-Matamoros G, Randles S, Walhout B, Gough C and Lindner R (2016) 'Responsibility Navigator', ResAGorA Project, Fraunhofer Institute, Karlsruhe.

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standard for medical products. The introduction to that standard explains why – bluntly stating that 'safety and quality are non-negotiables in the medical devices industry'.[50]

> ***ISO13485 is the main ISO quality norm for medical products. This means we have to have a quality management system in place, quality control procedures. You have to develop test plans, validation plans, test cases and, most of all, document the result(s). (Participant)***

Other standards are very relevant, notably ISO 13131 for telehealth services.[51] The latter, without the same strength of affirmation (as ISO 13485), 'provides advice and recommendations on how to develop quality objectives and guidelines for telehealth services that use ICTs to deliver healthcare over long and short distances by using a *risk management process* [their emphasis]'. There is, of course, a much longer list of standards relating to particular healthcare sectors that can be added to by codes of practice.[52]

The foregoing provides the context for the roadmap which is described in the next section.

# 5. Biomedicine Roadmap

Our work within the COMPASS (710543) project notes that 'responsibility' in relation to innovation in the healthcare sector is strongly influenced by the particular (ethical) concern to 'do no harm'. However, this simple commitment, enshrined in both the Hippocratic Oath and Nightingale Pledge, is an insufficient foundation on which companies that design, manufacture or supply healthcare technologies and services can base their approaches. The features (noted earlier in this report) give the reasons for this insufficiency by pointing to the changes to the market context and the inevitable moves to new service models. The impact, partly foretold by Christensen et al (2009), will be increasingly profound. It is impacting and will continue to impact on the technologies and how they are used in healthcare – by both manufacturers, service providers and service users (people or 'patients').

The roadmap that follows draws from the findings of the project. It is placed within the context of change that has been indicated. These changes demand high levels of attentiveness, anticipation and reflexivity by companies involved in the sector – being alert to 'market' change (as well as opportunity) and ready to act in the face of (new) knowledge.[53] There are, in fact, some fundamental company management requirements indicated in the roadmap. These are certain understandings and precautionary actions that need to be in place at the time the design (and innovation) process begins. An immediate commitment to such fundamentals is considered here as an aspect of 'responsible innovation' with an accompanying commitment to make progress in other areas of RRI where such an expectation is reasonable.

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[50] See https://www.iso.org/iso-13485-medical-devices.html. International Organization for Standardization (2016) 'Medical Devices', Geneva.
[51] See https://www.iso.org/standard/53052.html. International Organization for Standardization (2014) 'Health Informatics – Telehealth Services – Quality Planning Guidelines', Geneva.
[52] An example of the latter is the International Code of Practice for Telehealth Services developed by the Telehealth Quality Group. See www.telehealth.global.
[53] Stilgoe et al (2013) op cit. Anticipation is a further 'dimension' of RRI.

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## 5.1. How to Use the Roadmap

To use the roadmap, it is worthwhile investigating whether the initial company management aspects required are already embedded within the company's structure and practices. It is important to note that these, although called fundamental, may require some time and expertise to put into place. They are also often ongoing activities, or may be activities that require specific expertise or assistance in implementation. However, they are considered here as fundamental as they should be considered for part of the fundamental practices of the business.

The specifics of the roadmap in the implementation phase shows how the aspects of the roadmap need to link together throughout the entire research, design, production, marketing, and after-sales stages of development. Dotted lines represent feedback; solid lines represent the transitions between stages. It is important to note the role external engagement plays throughout this process – without external feedback into all stages (and not just testing or market research) the process cannot be considered responsible.

For this roadmap it is also important to understand who constitutes a "user". In this context we define "user" in a deliberately vague way – different companies are likely to have different users, perhaps patients, families, carers, doctors, etc. which they should reflect upon in terms of who is likely to be impacted and therefore needing to participate in user feedback mechanisms.

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## 5.2. The Roadmap

### COMPANY MANAGEMENT

**Vital**

- Developing, reviewing or re-affirming mission statement in order to set context for responsible innovation that can include new service frameworks – to meet the health needs of people who may be dependant or independent (and actual or potential self-managers).
- Ensuring commitment at all levels to ethical and safe modes of operation for products and services at stages of (a) research; (b) design and preparation; (c) production; (d) marketing and sales; and (e) purchase and usage in both healthcare and home settings (as applicable).
- Recognising the importance of data security, etc. (in the context of the GDPR) and the particular regard that needs to be taken for (safeguarding of) health data.
- Demonstrating readiness to engage with and respond to feedback from customers, end users (patients), etc., and involving them in decision-making process where appropriate.
- Demonstrating a commitment to semantic, technical, organisational and legal interoperability for technologies and communications that relate to health (in both clinical and preventative contexts).
- Adhering to codes of practice and applicable standards. Obtaining certification after compliance established via an accredited external agency, where appropriate.
- Working and collaborating with a relevant industry body with a shared ethos and, with or independently of it, to contribute to standards development in the field.
- Continuing adherence to the crucial values around care (and 'doing no harm') but seeing this in a new context of digital health that includes e.g. wearable and implanted devices, robotics and AI.

**Desirable**

- Being forward in raising public awareness of issues for health technologies and, in particular, their potential for empowering consumers and service users.

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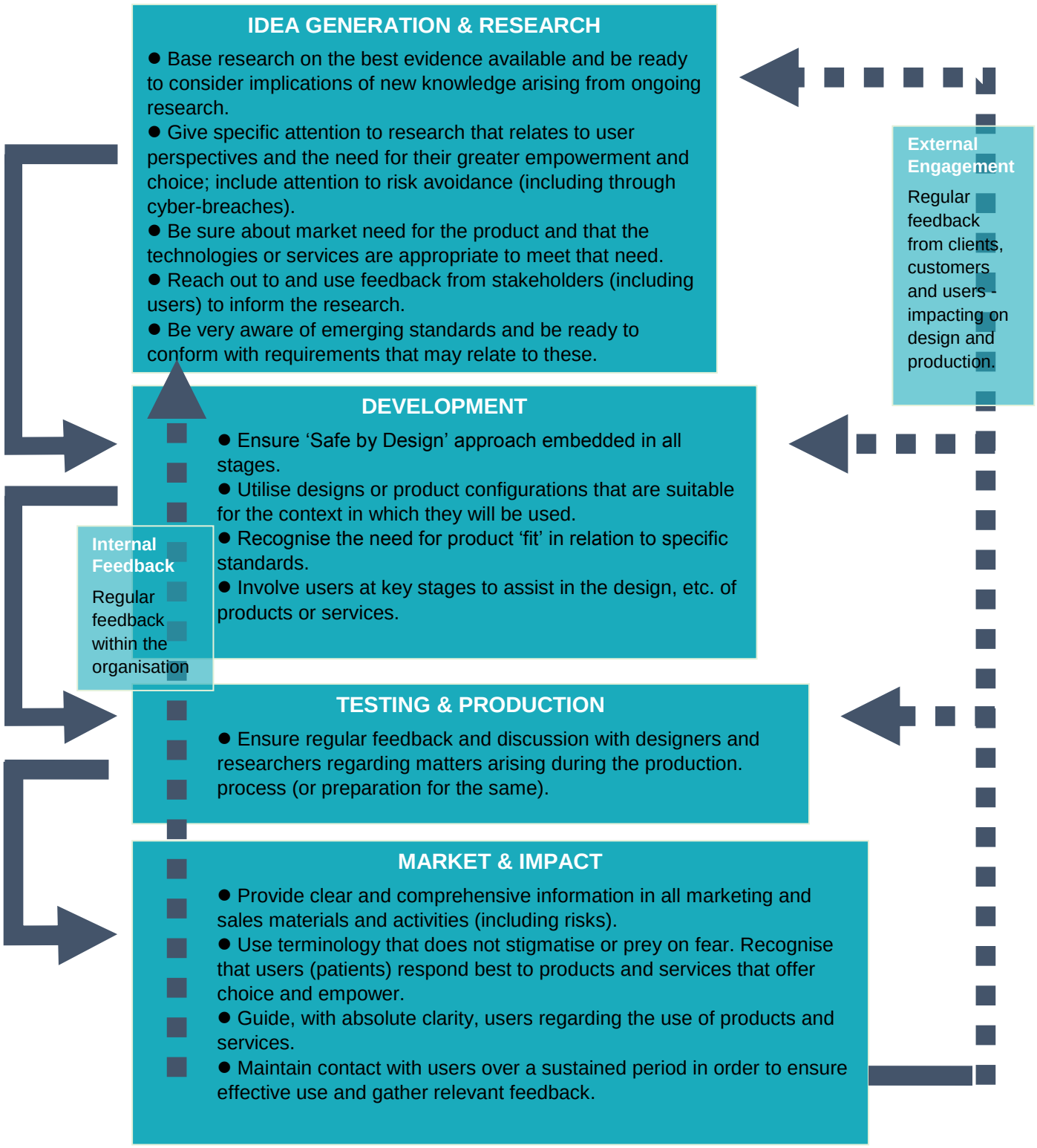


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