



CHERRIES
RESPONSIBLE HEALTHCARE ECOSYSTEMS

RRI in Health. General resources for understanding and framing RRI in the healthcare sector.

Constructing Healthcare Environments Through Responsible Research Innovation and Entrepreneurship Strategies, CHERRIES project will support Responsible, Research and Innovation (RRI) policy experiments in the healthcare sector in three European territories: Murcia (ES), Örebro (SE) and the Republic of Cyprus (CY).

March 12th, 2020



Document Control Sheet

Grant agreement number	872873
Project acronym	CHERRIES
Project website	www.cherries2020.eu
Deliverable number	D3.1 - RRI & Experiment Toolbox
Work package number	WP3 (Task 3.1)
Task Leader	Knowledge & Innovation (K&I)
Nature	Report
Dissemination level	Public
Delivery date	Due date: 31/12/2020 - Actual date: 29/01/2021
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Project Coordinator	ZSI
Executive summary	<p>This document is part of the toolbox (Deliverable D3.1). The toolbox collects and adapts RRI-related knowledge, tools, and other resources to support stakeholders and territorial partners in the implementation of the three CHERRIES experiments. Based on the screening and selection of RRI promising practices in health, the toolbox incorporates existing resources from European and national projects and activities focusing on RRI, RIS3, and healthcare interface. The toolbox, which will be put online on the CHERRIES website, includes the introduction and two parts. The present document is the first part, titled "RRI in health. General resources for understanding and framing RRI in the healthcare sector", provides the general framework in which the definition and the implementation of RRI-oriented demand-driven innovation initiatives in healthcare should be placed. The second part, titled "RRI demand-driven innovation approach", is organised according to the phases of the CHERRIES methodology and presents, for each of them, a set of resources useful for its implementation.</p>



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement n° 872873. This document reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.



Versioning & Contribution History

Version	Date	Author/Editor	Contributors	Comments
1.0 First draft version	January 7, 2021	Claudia Colonnello and Maresa Berliri (K&I)	Federico Marta and Paolo Signore (K&I)	
1.1 Internal revision of the first draft	January 13, 2021		Luciano d'Andrea, Alfonso Alfonsi and Gabriele M. Quinti (K&I)	
2.0 Second draft version	January 16, 2021	Claudia Colonnello, Maresa Berliri (K&I)	Federico Marta (K&I)	
2.1 Shared with Project partners	January 18, 2021		Project Partners	
3.0 Final version	January 28, 2021	Claudia Colonnello, Maresa Berliri (K&I)		
3.1 Final incl. QA	February 5, 2021		Stefan Philipp	

Document last saved on 07/02/21



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PART ONE

RRI in Health. General resources for understanding and framing RRI in the healthcare sector



This Part of the Toolbox provides the general framework in which the definition and the implementation of RRI-oriented demand-driven innovation initiatives in healthcare should be placed.

The part is organised into three sections.

- Section One briefly accounts for the deep transformations which have been affecting science for the last decades, which represent the general context in which RRI is placed.
- Section Two deals with the main changes challenging healthcare R&I systems, i.e., the sector the CHERRIES Project and the territorial RRI pilot experiments are focused on.
- Section Three introduces the concept of RRI and dwells upon the application of RRI principles and tools in general and, specifically, in the health sector.

Throughout this Part, links to resources are provided for better interpreting and framing RRI in health, innovation and in the territorial dimension, also including examples of relevant projects and initiatives. Some of them are also presented in Part Two.

1. A new framework for science and society

Science and Technology undoubtedly are one of the main driving forces in modern times and might contribute to tackle societal challenges of our times. Nevertheless, they are presently facing complex societal challenges and are undergoing fast changes, especially affecting how they are socially managed and perceived. In this section, some of these challenges and changes will be briefly discussed.

1.1. Science is changing

In general terms, [scientific research and innovation are experiencing a complex transition](#). Different interpretive models have been developed to account for it, including the Mode 1/Mode 2 model of scientific knowledge production, the Post-academic science, the Post-normal science, the Triple Helix approach, the Academic Capitalism, or the Innovation System.

Although in different ways, they overall describe the “paradigm shift” still occurring from the consolidated social model of science, often expressed with the image of the “**Ivory Tower**”, to an emerging model, sometimes referred to as “**Open Science**”.

The main features characterising this shift are summarised in the box below.



Box: The Paradigm shift in the social model of science

The **consolidated social model of science** sees it as:

- Substantially autonomous from society
- Largely separated from the facts, worries, and practicalities of society and, in general, of the real world
- Based on forms of self-direction (it mainly advances on the basis of scientists' interests)
- Internally organised in well-defined disciplinary fields
- Not involved in the actual implications and use of its outputs (in terms of knowledge, discoveries, technologies, but also impacts and risks).

The **emerging model** thinks science as:

- Fully embedded in society and strongly connected with political, economic, and societal dynamics (*de facto* limiting its autonomy)
- Open to the external lay actors and sensitive towards expectations, needs, worries and problems of society
- Increasingly adopting multidisciplinary approaches
- Based on forms of co-direction and co-production with stakeholders and the public at large
- Directly concerned with the actual implications and use of its outputs.

Source: FIT4RRI Guidelines, Chapter One Changes affecting science, 2020

This transition is not proceeding in a linear way and contradictions also emerge. For example, while the disciplinary boundaries are weakening, the application fields are rapidly expanding and fragmenting into thousands of research strands. Moreover, the organisational ways to produce research are changing, with the effect to make science less and less a unitary, ordered, and consistent entity. Science-society relationships are also more problematic and complex, the access of research organisation to public resources is more uncertain and the public support to science is less evident and homogeneous.

This transition is not only altering the quality of science relations with other sectors of society, but is also modifying its most basic and intimate mechanisms, related to the very production of “scientific knowledge” (for example, the reproducibility of data or the evaluation of research quality) with impacts on the contents of the scientific research and, sometimes, on the epistemological ground of disciplines.

1.2. Society is changing

The changes occurring in science are part of a wider array of transformations touching contemporary societies as a whole, usually referred to as the [shift from modern to post-modern or late-modern society](#).

The globalisation processes affecting any social sphere and the diversification of cultures and values are leading to a general weakening of social structures, including political, religious, and state institutions, especially against the increasing capacity and autonomy of individuals and the groups they are part of, e.g., in making their own choices, in developing their own worldviews, or in triggering social changes. The weakening of social structures is also making people more exposed to risks of a different kind (health risks, environmental/climate change risks, weakening of welfare, etc.) and making the boundaries among social institutions and among social spheres more blurred and uncertain.



Like any other social institution of modernity, also science is now put under pressure because of these broader transformations. For example, globalisation is propelling a harsh competition among research organisations on a global scale; the growing presence of non-academic organisations involved in research and the expanding demand to turn scientific research results into marketable products in a short time are making the boundaries of science more uncertain and penetrable by, e.g., policymakers, industries, citizens and citizen groups.

1.3. The relations between science and society are changing

As said above, these transformations are particularly affecting science-society relations.

Science and society are interconnected entities: they have always co-evolved in some way. However, their interaction is now more problematic, for different factors, such as:

- The decreasing authoritativeness and social recognition of scientific institutions, often leading to anti-science attitudes and pseudo-scientific beliefs (see, for instance, the no-vax and the no-mask movements)
- The ever-stronger connection between science and ethical and policy issues, triggering and feeding social tensions on controversial issues and “public battles” among experts
- The increasing sensitiveness of the public towards science-related risks
- People’s decreasing trust in scientific institutions, leading to a growing demand for accountability and transparency
- The need for science institutions to increasingly demonstrate their social and economic usefulness to citizens as taxpayers.

These and other factors are plunging science and technological innovation into a paradoxical condition: while they are increasingly important for people’s life and future, they are also more and more socially weak. Specific risks raised, in particular, by an inadequate connection between science and society, concern:

- The disconnection of science from the needs and demands of society, with the consequence to make science unable to successfully address key societal problems
- The decreasing capacity of science to be inclusive with respect to, e.g., women, youth, or minority groups, with the consequence of waste precious human resources
- The incapacity of science to fully exploit the knowledge produced because of, e.g., conflicting relations with external actors, distortions due to power dynamics or lack its decreasing social status
- The risk for science to be more and more questioned (see some controversial issues such as vaccination, the use of GMOs, animal experimentation, the use of stem cells, pharmacological research, atomic energy, etc.), with the consequence to further decrease the authoritativeness of science and researchers or to get involved in broader social tensions and conflicts.

The overall picture is anyhow ambiguous. For instance, the increasing openness of science towards society is both leading to social conflicts and controversies but is also favouring the [emergence and consolidation of new participatory approaches](#), such as citizen science.

The trajectory and outputs of this transition are still unclear. Nonetheless, there is an increasing perception by key science actors of the need to revise the usual [mechanisms of governance of science for anticipating](#)



[and managing risks and opportunities](#). This is perhaps even truer in this period of great emergency related to COVID-19.

2. Trends in the healthcare sector and healthcare R&I system

2.1. Four main challenges

As stated in the [Horizon 2020 – Work Programme 2018-2020 Health, demographic change and wellbeing](#), Europe is facing four main challenges related to healthcare:

- The rising and potentially unsustainable health and care costs, mainly due to the increasing prevalence of chronic diseases, to an ageing population requiring more diversified care, and to increasing societal demands
- The influence on the health of external environmental factors including climate change
- The risk to lose the ability of healthcare systems to protect the populations against the threats of infectious diseases (as witnessed by the COVID-19 pandemic)
- The presence of health inequalities and problems in access to health and care.

These challenges are not only leading to an increase in the demand for healthcare services but are also driving towards more personalised treatments while healthcare systems are facing constant pressure to reduce costs, to improve the quality of healthcare provisions, and to focus more on prevention and health promotion.

2.2. Innovation trends

Thus, innovation is becoming a critical factor for healthcare organisations to successfully face these challenges¹.

However, orienting and managing innovation processes can be problematic. [The scientific and technological breakthroughs which are transforming the future of medicine and health inevitably produce new risks and have societal implications that need to be addressed proactively](#). In the same way, the introduction in the health systems of a steadily growing number of Health 4.0 and other innovative new technologies (e.g., wearable devices, robotics, genomics, artificial intelligence, 3D printing, mobile applications, etc.) raise complex challenges for all the relevant stakeholders of the R&I healthcare system, including policymakers, regulatory authorities, payers, physicians, and patients.

¹ See: Larisch, L. M., Amer-Wählin, I., & Hedefjäll, P. (2016). Understanding healthcare innovation systems: the Stockholm region case. *Journal of Health, Organisation and Management*, 30(8), 1221–1241; Marjanovic, S. et al. (2020). Innovating for improved healthcare: Sociotechnical and innovation systems perspectives and lessons from the NHS. *Science and Public Policy*, 47(2), 283–297; Proksch, D., Busch-Casler, J., Haberstroh, M. M., & Pinkwart, A. (2019). National health innovation systems: Clustering the OECD countries by innovative output in healthcare using a multi indicator approach. *Research Policy*, 48(1), 169–179.



Examples of trends, partially overlapped, occurring at the crossroad between science, innovation, and health are mentioned below².

- **Digital transition.** The digital transition occurring in the healthcare sector is showing great potentials in transforming working models and in improving the patients' clinical experience. However, it entails new ethical, legal, and social implications to handle, related to the design, development, and deployment of mobile health, telehealth and telemedicine solutions, the creation of open data platforms, and new digital data infrastructures (reliability, security, privacy, and data management issues), the interoperability among technological systems and healthcare providers, or issues related to the digital divide issues.
- **Self-management innovations.** Another trend is the [adoption of technological devices allowing patients to cooperate in healthcare treatment](#). It is a promising approach to improve outcomes and reduce the healthcare costs associated with chronic conditions.
- **Patient-centred care (PCC) approach.** The increasing [involvement of patients in all decisions](#) about their health is becoming a new paradigm for cost-effective provision of health care, even though it is facing also obstacles related to, e.g., the organisation of healthcare service providers and the professional culture of health workers.
- **Precision medicine.** [Precision medicine is an emerging approach](#) potentially able to profoundly modify healthcare systems and represents a great opportunity for the advancement and the optimisation of care treatments. However, it could have also negative impacts, for example, worsening the existing healthcare disparities or even introducing new forms of inequality among different segments of the population.
- **Public participation in health policy.** [Patients and citizens are increasingly recognised as key actors and partners](#) in the decision-making processes pertaining to healthcare and health research. This is also leading to new forms of scientific citizenships or "active patientships".
- **Participatory medicine.** This concept partially overlaps with other trends mentioned above. It refers to the demand for a general paradigm shift in medicine toward the so-called "[P4 Medicine](#)", i.e., a Predictive, Preventive, Personalized, and Participatory medicine.
- **Open innovation 2.0.** In this case, the focus is on [the adoption of the open science and innovation principles to healthcare](#), allowing, for example, the development of open platforms for social innovation and for the involvement of patients in the innovation process (Patient Innovation).
- **User-driven innovation.** This trend has to do with the growing tendency also in health-related innovation to [tailor new products and services to users' needs](#), recognising then a proactive role in the innovation process.

² For a broader description of the theoretical background on pressing challenges and innovation trends in health relevant within the Cherries framework, a reference is made to the introductory section of the D3.2 devoted to the presentation of the Cherries methodology.



These trends, already very fast because of the globalisation and other driving transformational forces, [are now further accelerating because of the COVID-19 pandemic](#). They also require better integration of organisational, clinical, societal, and ethical considerations into the research process as well as into the [design and development of medical innovations](#).

2.3. Territorial level

Health systems face persisting [challenges also at territorial level](#). They include, for instance:

- Providing equal access to care to the population living in remote regions
- Ensuring timely access to health services,
- Achieving greater care coordination for people with chronic diseases.

The “glocal” dimension of recent health crises (as the surge of COVID-19 pandemic) amplified these challenges and highlighted the priority need to achieve “better health for all” at the territorial level.

The territorial level plays a pivotal role also for what concerns health research and innovation. Based on an innovation system approach, healthcare innovation can be understood as “driven by localized and endogenous interactions across various units and organisations, coordinating mechanisms (i.e., the institutional milieu), and growing interdependencies across different domains (i.e. scientific research, regulation, delivery of patient care and the market process)³”.

It is to highlight that the increasing involvement of stakeholders in both healthcare provision and innovation may entail complex social negotiation processes, due to conflicting interests and views, with significant differences in the balance of power of the different stakeholder groups. This is also the reason why healthcare innovations “rarely achieve widespread uptake even when there is robust evidence of their benefits (and especially when such evidence is absent or contested)⁴”.

³ Consoli, D., & Mina, A. (2009). An evolutionary perspective on health innovation systems. *Journal of Evolutionary Economics*, 19(2), 297–319.

⁴ Greenhalgh, T., & Papoutsi, C. (2019). Spreading and scaling up innovation and improvement. *BMJ (Online)*, 365. <https://doi.org/10.1136/bmj.l2068>



Further readings

Besides the resources inserted in the text of this chapter, here below other few useful readings are provided, concerning ongoing trends and changes affecting the health sector

- [Predictive, Personalized, Preventive and Participatory \(4P\) Medicine Applied to Telemedicine and eHealth in the Literature](#) (2019)
- [New methods for user-driven innovation in the health care sector: Report on six pilot projects in which are tested user-driven innovation in the health care sector](#) (2009)
- [Medical Technology in Healthcare and Society](#) (2009)
- [Innovation in the Era of Experience: The Changing Role of Users in Healthcare Innovation](#) (2016)
- [World Economic Forum, Health and Healthcare in the Fourth Industrial Revolution Global Future Council on the Future of Health and Healthcare](#) (2016-2018)
- [When patients become innovators](#) (2019)
- [Interacting Patients. The construction of active patientship in quality improvement initiatives](#) (2016)
- [Assessing Patient Participation in Health Policy Decision-Making in Cyprus](#) (2016)
- [Public and patient participation in health policy, care and research](#) (2017)
- [How can we assess the value of complex medical innovations in practice?](#) (2017)

3. An introduction to Responsible Research and Innovation

As illustrated in the previous sections, transformations in late-modern societies and in science pose new governance challenges for Science and for R&I healthcare systems, at the local, national and global levels. RRI, like other similar approaches, wishes to contribute to facing such governance challenges.

In this section, a brief introduction to RRI is provided. It is out of the scope of this section to provide an extensive and comprehensive overview on RRI in health and of the different aspects of the CHERRIES methodology (need-demand driven approach, Open and User Innovation, co-creation). In this regard, reference is made to Part Two of this Toolbox and to the official document illustrating the CHERRIES methodology and Model (D.3.2).

3.1. History

Research and Innovation (RRI) is a policy framework that emerged from a particular concern in European policy circles that increasing expenditure on research and innovation was not failing to lift general welfare levels up. The launch of RRI also follows the [2009 Lund Declaration](#), updated in 2015, which called upon European nations and institutions to focus research on the 'grand challenges' facing society, such as climate change, water shortages, and ageing populations.

The [RRI concept](#) was developed within the EC, starting as a policy rather than an analytical concept. Subsequently, the Directorate-General for Research promoted RRI as an ambitious challenge for the formulation of research and innovation policies driven by the needs of society and engaging all societal actors via inclusive participatory approaches. RRI was included as a cross-cutting action in the EU Program Horizon 2020 – the world largest research and innovation programme – at its establishment in 2014.



RRI can also be found in [Europe's policy of 'Open Innovation, Open Science and Open to the World'](#), launched in 2016, focusing on the advent of digital technologies as a powerful tool to make science and innovation more open, collaborative and global and able to interact more effectively with societal actors.

In these last decade, [RRI has also become the focus of research programmes launched by several national research funding](#) bodies, such as the Netherlands Council for Research (NWO), the UK Engineering and Physical Sciences Research Council (EPSRC), the US National Science Foundation (NSF) and the Research Council of Norway.

RRI has gained recognition over time as a guiding principle for EC research policies and has been incorporated into "Europe 2020", the new Framework Programme that will run from 2020 to 2027.

3.2. Definitions

Different definitions and perspectives have been elaborated on RRI in different geographical and organisational contexts. Some of the most common definitions are reported in the box below.

BOX: Some of the most common and consolidated definitions of RRI

"Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)⁵."

"Responsible Research and Innovation means that societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European society. RRI is an ambitious challenge for the creation of a Research and Innovation policy driven by the needs of society and engaging all societal actors via inclusive participatory approaches⁶."

"Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present (...) RRI claims for an alignment of science and innovation to values, ethical standards and expectations of society by making them more: Reflexive; Anticipatory; Responsive; Inclusive⁷."

A common point shared by different authors is the need to develop governance structures that direct or re-direct research and innovation towards societally desirable outcomes, by both mitigating the negative effects of innovation in areas with potentially adverse societal effects and actively supporting innovative activities in areas where the societal benefit is expected to be high (for instance, in addressing the societal challenges Europe and the World are facing, like climate change, food security and demographic change).

⁵ von Schomberg, R. (2011). *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields*.

⁶ European Commission (2014). Rome Declaration on Responsible Research and Innovation. Available at: https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21_November.pdf

⁷ Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy*, 42(9), 1568–1580.



This implies making science and technology able:

- To include a diverse range of partners and voices to plan, co-create and co-develop marketable solutions
- To align to values, expectations, and need of society
- To anticipate their own unexpected impacts
- To transparently share knowledge and ideas
- To connect people and institutions in different disciplines, sectors, and countries.

In a broader perspective, RRI can be interpreted as one of the organised and policy-oriented reactions to the transition of science (see Section One) and to the uncertainty this latter generates in the research systems and in the society as a whole. In theoretical terms, it can be also understood as including any effort for overcoming the fragmentation characterising science as a social institution and for coordinating all the actions aimed at governing the transitional processes affecting science.

As for CHERRIES, the working definition built on previous efforts in the framework of the RRI Tools Project fits well also with the aims and the framework of the project. RRI is described as a “dynamic, iterative process in which all stakeholders in research and innovation become mutually responsive and share responsibility for both the process and its outcomes”. This means the focus is not only on achieving socially desired outcomes, but also on how the research and innovation (R&I) that leads to them is conducted and on those involved in this process.

3.3. The RRI keys

In practical terms, the European Commission developed an RRI policy framework including 6 keys or pillars:

- **Public Engagement** – This key is aimed at engaging society more broadly in its research and innovation activities
- **Open Access** – This key focuses on the need to increase access to scientific results (research data and publications)
- **Gender Equality** – This key is concerned with ensuring gender equality in both the research process and research content
- **Research Ethics and Integrity** – This key is aimed at ensuring due consideration of the ethical dimension of research and research practice throughout the research process
- **Science Education** – This key concerns the promotion of formal and informal science education in any social sector, including youth, elderly people, and disadvantaged groups
- **Governance** – This key is intended to favour the development of harmonious governance models for responsible research and innovation able to integrate the previous 5 keys.

These keys can be understood as possible vectors or areas of change to make R&I a more inclusive process, to ensure excellent scientific outputs, and to prevent and cope with the main risks the European research



and Innovation may produce, with a focus on those raised by an inadequate connection of science with society.

RRI keys also represent the axes of a policy agenda for fostering structural changes within research organisations, through both specific actions and more systematic RRI-oriented plans.

3.4. The RRI process

Beside the definition of RRI as policy framework hinged upon the 5 RRI keys, many authors prefer to approach RRI in terms of specific **process dimensions** which, separately or in combination, are supposed to induce changes in research and innovation practices, science policies, or scientific culture.

Although positions may differ, a general convergence can be found on four main dimensions of RRI – **anticipation, reflexivity, inclusion and responsiveness** – understood as “the four conditions can be seen as necessary devices for reflection that will give shape to the research and innovation process by cultivating a forward-looking approach to responsibility⁸”.

- **Inclusion.** It mainly refers to the engagement of different stakeholders from the early stages of research and innovation onward so as to give voice to all the concerned interests, values, needs, and beliefs.
- **Anticipation.** It refers to the capacity of envisioning the future of R&I and understanding how current dynamics help design the future in order to prevent risks and to lead research to desirable impacts. Hence the importance recognised for implementing RRI to reliable and participatory forecasting techniques.
- **Responsiveness.** It concerns the capacity to develop proactive management of new technologies so as to identify risks and develop ethically adequate responses. The concept of responsiveness also relates to transparency (responses should be open to the public debate) and accessibility (scientific results about risks and responses should be openly accessible to everyone). As it is easy to notice, responsiveness is partially overlapped with the dimension of anticipation.
- **Reflexivity.** It is mainly seen as the capacity of the research system to keep control of its own activities and assumptions, to be aware of the limits of the knowledge produced and of the framing processes connected to the identification of the issues to be addressed as well as to reflect on values and beliefs connected with R&I. Reflexivity is linked to public dialogue and collaborative approaches in science.

RRI process dimensions are useful for shaping the **directionality of R&I progresses** for the benefit of society. RRI is about **anticipating** how our decisions regarding research and innovation might shape the future and about **reflecting** on the actions to take while being **open** and **transparent** about these decisions and actions. It should not merely recognize the needs and wishes of stakeholders, but also **shape directions of research and innovation in response to a diverse set of perspectives and to changing circumstances**.

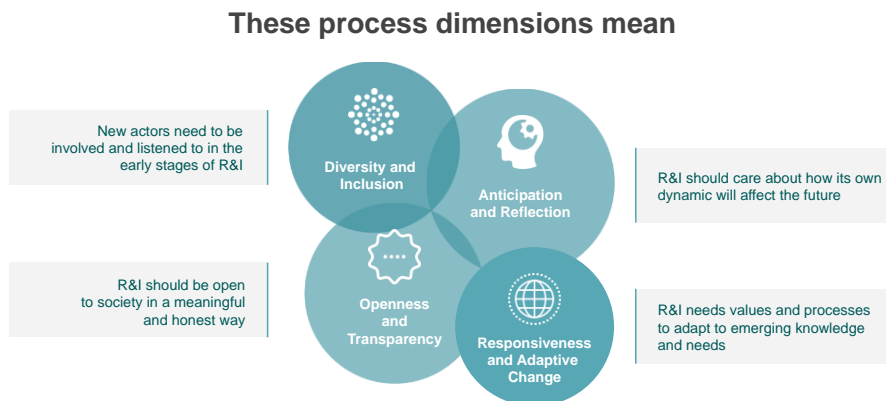
RRI aims to create a society in which responsibility for our future is shared by all people and institutions involved and in which research and innovation practices strive towards ethically acceptable, sustainable, and

⁸ Nielsen, M. W., Mejlgaard, N., Alnor, E., Griessler, E., & Meijer, I. (2018). Ensuring Societal Readiness: A Thinking Tool. Available at: https://newhorizon.eu/wp-content/uploads/2019/10/Deliverable_6.1_THINKING_TOOL.pdf



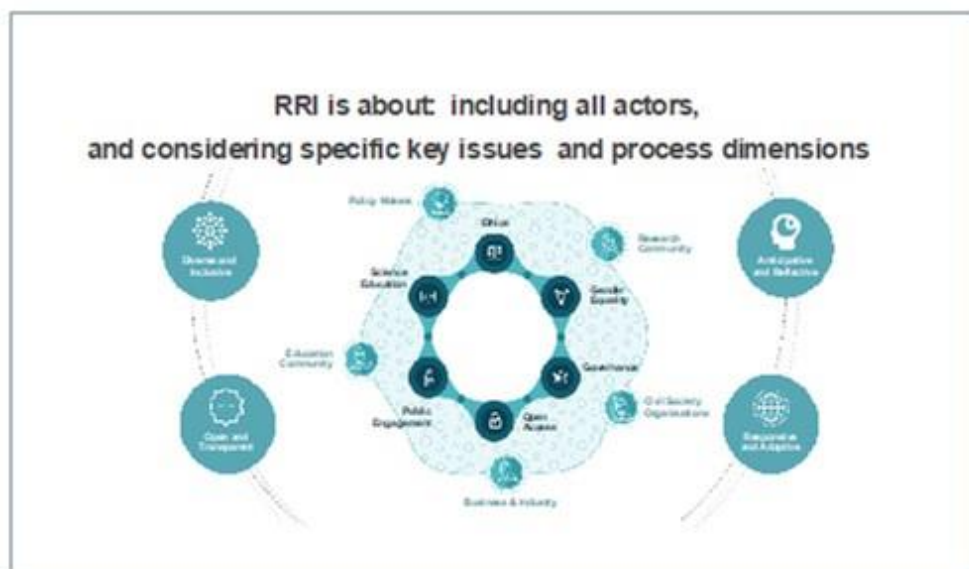
socially desirable outcomes.

In the **CHERRIES perspective**, four couples of dimensions of the RRI process defined within the RRI Tools project are considered, i.e., Diversity and Inclusion, Anticipation and Reflection, Openness and Transparency, Responsiveness, and Adaptive Change. Their meaning is summarised in the figure below.



Source: A Practical Guide to Responsible Research and Innovation: Key Lessons from RRI Tools, 2016

These dimensions interact with the other components of the RRI process, i.e., the different RRI keys and the different stakeholders involved in the process. These relations are visualised in the figure below.



Source: A Practical Guide to Responsible Research and Innovation: Key Lessons from RRI Tools, 2016



This process can be assessed also in terms of the expected outcomes. At least three kinds of outcomes can be identified:

- Learning outcomes (e.g., engaged public, responsible actors, responsible institutions)
- R&I outcomes (ethically acceptable, environmentally sustainable, and socially desirable innovations)
- Societal outcomes (finding solutions to the major societal challenges Europe is facing).

Further useful resources on RRI

- [Introduction to the *International Handbook on Responsible Innovation* \(2019\)](#)
- [Responsible Research and Innovation: From Science in Society to Science for Society, with Society \(2012\)](#)
- [Responsible Innovation and Responsible Research and Innovation \(2019\)](#)
- [RRI in a Nutshell \(2018\)](#)
- [A Practical Guide to Responsible Research and Innovation \(2016\)](#)
- [Europe's Ability to Respond to Societal Challenges \(2012\)](#)



3.5. Territorial RRI

The CHERRIES Project focused on the application of RRI principles at a territorial level (Territorial RRI)⁹. EU Regions are starting recently to address RRI and they are facing common challenges in the understanding and implementation of this approach at territorial level¹⁰.

The concept of Territorial RRI is partially overlapped with other approaches such as open innovation, territorial innovation, or innovation *milieu*. However, in the Territorial RRI, the focus is on fostering more open, inclusive, reflexive, and responsive governance of the R&I regional policies and strategies. This could allow overcoming the usual criticisms toward regional R&D planning and the RIS3 process (the approach to innovation focusing on the development of national and regional research and innovation strategies for smart specialisation). These criticisms mainly concern the tendency to involve only experts in territorial dialogue initiatives, the tendency to ignore future challenges, opportunities, and even positive externalities of the innovation processes and the tendency of the stronger stakeholders (corporations, universities, etc.) to “hijack” the policy agenda and the policy process.

Similarities and differences between Territorial RRI and other approaches can be also found. Fitjar¹¹, for example, compare RRI with RIS3, identifying the following similarities:

- Both look for broad stakeholder involvement in the development of research and innovation policies
- Both orient research and innovation towards the solution of the grand societal challenges
- Both have been defined as a policy concept rather than as a theoretically motivated framework.

As for the main differences:

- RIS3 is primarily oriented towards regional competitiveness and therefore does not fully incorporate local institutions and lacks reflexivity on public and social values
- RRI is mainly aimed at reconciling scientific progress with societal interest to avoid loss of legitimacy but lacks spatial and geographical dimensions (innovation processes are socially and spatially embedded) and is not explicit about the local perception of what is “responsible” or socially desirable.

A virtuous integration between RRI and RIS3 might be therefore useful for more open, reflexive and responsive innovation policies for local growth and social cohesion and for tackling European innovation challenges at territorial level.

Another view on Territorial RRI interprets it in terms of sustaining local actors in taking care of and becoming

⁹ “Territorial RRI” is the aim of the program SwafS-14-2018-2019-2020: Supporting the development of territorial Responsible Research and Innovation:
https://ec.europa.eu/research/participants/data/ref/h2020/other/guides_for_applicants/h2020-swafs-14-18-19-20-policy-briefing_en.pdf

¹⁰ Raj Kumar Thapa, Tatiana Iakovleva & Lene Foss (2019), “Responsible Research and Innovation: a systematic review of the literature and its applications to regional studies, European Planning Studies:
<https://www.tandfonline.com/doi/full/10.1080/09654313.2019.1625871>

¹¹ Fitjar, R.D., Benneworth, P., & Asheim, B.T. (2019). Towards regional responsible research and innovation? Integrating RRI and RIS3 in European innovation policy. *Science and Public Policy*, 46(5), 772-783.



responsible for their territory, thus facing the factors leading to de-territorialisation (i.e., a social and economic impoverishment of the territory) and promoting re-territorialisation. This means making local actors as part of the “territory-making process” meant as an ongoing and open-ended process of establishing and cultivating new transformative relationships for territorial governance.

Box: Some European projects focusing on Territorial RRI

Some European projects are specifically focused on the integration of RRI framework within territorial innovation policies and strategies, developing RRI-related SR3 Action Plans (e.g., INTERREG Europe [MARIE project](#)) or implementing territorial experiments, aimed at integrating RRI within RIS3 (e.g., the EU SWAFS [TeRRItoria project](#)).

Some examples of good practices within the framework of the project MARIE are reported within the document “[When responsible innovation meets the smart specialisation strategies](#)”.

Other examples of practical implementation of RRI in regional smart specialisation strategies from the three EU ‘SWAFS 14’ projects TeRRItoria, [SeeRRI](#) and [RRI2SCALE](#) were presented during the Triple Helix Association Summit (Nov. 2020) within a workshop promoted by the TeRRItoria Project, titled “[Introducing RRI principles to enhance regional innovation policies, including RIS3](#)”. The workshop was focused on the role of Responsible Research & Innovation (RRI) as a facilitator to enhance citizen participation and societal impact on local and regional.

Another example of inclusion of RRI elements within the priorities of the RIS3 regards the Värmland Region in North Central Sweden. As reported in this article on “[Territorial Approach to Smart Specialisation: Experience from Värmland](#)”.

3.6. RRI in health

Looking at the different RRI-oriented experiences in biosciences and medical research, it is worth noticing that there are no rigid and universal models, adaptable anytime and anywhere.

Although RRI is characterized as a whole by specific elements, formalized over time, it has an intrinsically “contextual” character. As suggested in the Starbios2 strategic document “[Mainstreaming RRI in biosciences and beyond: a quadruple contextualisation](#)”, **different frames of “Responsibility”** (meant as issues at stake concerning the relationship between science and society) are important for a mainstreaming of RRI at different levels:

- The organisational frame (going beyond the “business as usual”)
- The disciplinary or sectoral frame (adapting RRI to the sectoral challenges)
- The geopolitical and cultural frame (identifying what territorial challenges and needs and what territorial key actors to engage)
- The historical frame (preventing and responding to historical challenges, e.g., the COVID 19 Pandemic).

In the **healthcare sector**, the issue of making research and innovation more responsible could be of pivotal importance.



In fact, technological innovations can exert pressure on available resources¹². In publicly financed systems, this puts the State in a position where it fosters innovations with the aim of creating a competitive economy while, at the same time, it is the main purchaser of innovative and expensive medical technology. This is posting an enormous and increasing challenge to balance growing public health spending and providing patients with access to the best possible care.

Therefore, it is imperative that “new technologies resolve and not create problems for healthcare systems”. This led to the development of a new model for the design, development, and governance of medical innovation able to carefully examine **moral** and **social issues** and to encourage greater inclusion of the actors concerned by the innovation. The assumption is that such a model might be better suited to respond to the multiple challenges and needs of health care systems and make it easier for the State to manage the delicate trade-off between investments and control in the governance of medical innovations¹³. In this context, RRI could help to anticipate social risks and to reduce unforeseen and undesirable consequences of innovations.

It is to consider that responsibility is already embedded in healthcare systems since their creation in the 1970s and imposed through a set of long-standing rules and routines that govern the provision of medical services. These regulations require public and private actors to deliver the necessary services to maintain and improve the health and wellbeing of the population. Accountability is embedded in the policies and regulations that frame R&D, manufacturing and distribution of medical devices and pharmaceutical products by ensuring the quality, effectiveness, and safety of these products.

In this framework, according to Demers-Payette a specific role can be played by the RRI approach, i.e., contributing to identify innovation needs and to better integrate innovations within the healthcare system by providing a **future-oriented framework**. RRI is in fact more concerned with the dynamics that drive the innovation process. Therefore, it might help understand how responsible medical innovation could better address the needs and challenges of health care systems.

An attempt is also made by the authors to define the application scope of the RRI dimensions in healthcare innovations.

- The dimension of **anticipation** in healthcare innovations addresses the identification of new preclinical opportunities for innovation, as well as their social, ethical, and political risks.
- The dimension of **reflexivity** refers to a socio-political analysis of the context in which medical innovations are produced and used as well as to the assessment of the value system and societal practices governing R&D processes in healthcare.
- The dimension of **inclusion** has to do with the involvement of a wider public and users in R&D as well as with the development of mechanisms of public deliberation on health issues and medical innovation process.

¹² Demers-Payette, O., Lehoux, P., & Daudelin, G. (2016). Responsible research and innovation: a productive model for the future of medical innovation. *Journal of Responsible Innovation*, 3(3), 188–208.

¹³ Demers-Payette et al. (2016). Op. cit.



- The dimension of **responsiveness** concerns the ability to mobilise emerging views, norms, and knowledge in the R&D process and subsequently create funding, regulations, and audit processes that allow for an adaptive medical innovation process.

The application of these dimensions might offer the opportunity to reflect on the fore challenges of medical innovation that responsible medical innovation could address by articulating: (1) a clearer understanding of the uses of medical innovations and their context; (2) a better alignment between health and innovation value systems and social practices; (3) a sustained engagement of users and the public in the innovation process; and (4) flexible steering of innovation trajectories within a highly regulated environment.

Another approach inspired by the application of RRI is that of **Responsible Innovation in Health (RIH)**. It is defined as a “collaborative endeavour wherein stakeholders are committed to clarify and meet a set of ethical, economic, social and environmental principles, values and requirements when they design, finance, produce, distribute and use socio-technical solutions to address the needs and challenges of health systems in a sustainable way¹⁴”.

RIH refers to the innovation as well as to the organisation that develops and makes it available to intended users. The principles, values and requirements of RIH are applied throughout a technology’s lifecycle, promoting the best social and environmental practices.

In this sense, RIH is understood as a policy framework providing an integrated set of dimensions through which health and innovation policy-makers “can envision what types of innovations health systems need and how they should be produced and brought to market in order to support equitable and sustainable health systems around the world¹⁵”.

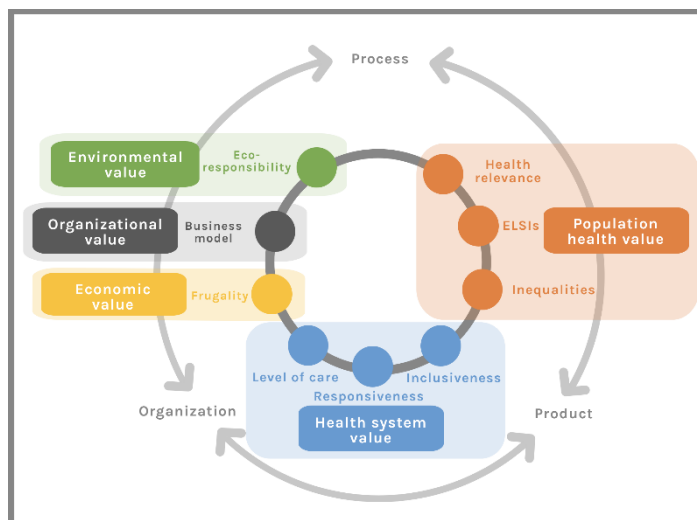
In such a perspective, five value domains have been identified as characterising RHI:

- Population health value (relevance, inequality, ELSI – ethical, social, and legal implications)
- Health system value (inclusiveness, responsiveness, level of care)
- Economic value (frugality, i.e., greater value with lesser resources)
- Organisational value (business models creating value for users, purchasers, and society)
- Environmental value (eco-responsibility).

The interaction between these values domains and the different components of innovation (process, organisation, and product) is schematized in the figure below.

¹⁴ Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J. L. (2018). Introducing responsible innovation in health: a policy-oriented framework. *Health research policy and systems*, 16(1), 90.

¹⁵ Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J. L. (2018). Op. Cit.



Source: InFieri Project, 2020

Further useful resources on RRI in Health and RHI

- [The Unexplored Contribution of Responsible Innovation in Health to Sustainable Development Goals](#), (2018)
- [Developing a tool to assess responsibility in health innovation: Results from an international Delphi study](#) (2018)
- [Responsible Innovation in Digital Health](#), (2019)
- [What Health System Challenges Should Responsible Innovation in Health Address? Insights From an International Scoping Review](#) (2018)
- [Nurturing Societal Values in and Through Health Innovations](#); Comment on “What Health System Challenges Should Responsible Innovation in Health Address?” (2019)
- [Innovation, demand, and responsibility: some fundamental questions about health systems](#); Comment on “What Health System Challenges Should Responsible Innovation in Health Address?” (2019)
- [When Desirability and Feasibility go Hand in Hand](#): innovators’ perspectives on what is and is not responsible innovation in health (2020)
- [Gender Equality in Science, medicine, and Global Health](#): where are we at and why does it Matter? (2017)
- [Global Health 50/50 Report](#) (2020)
- [Gender-Responsible Research and Innovation for Small and Medium-Sized Enterprises: Nanotechnology, ICT, and Healthcare](#) (2017)
- [Ethics of Healthcare Robotics](#): towards Responsible Research and Innovation (2016)
- [Tackling COVID-19 through Responsible AI Innovation](#): Five Steps in the Right Direction (2020)
- [Fostering the Common Good in Times of COVID-19: the Responsible Innovation in Health Perspective](#) (2020)
- [Emerging Technologies as the next Pandemic? Possible Consequences of the COVID Crisis for the Future of Responsible Research and Innovation](#) (2020)
- [Policy brief on Strengthen gender mainstreaming in WHO’s pandemic preparedness and response](#) (2020)

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement n° 872873. This document reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.