RRI & Experiment Toolbox
Toward Responsible Healthcare Ecosystems

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Executive summary	The toolbox (Deliverable D3.1) 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 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.

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Version	Date	Author/Editor	Contributors	Comments
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INTRODUCTION

1. THE CHERRIES PROJECT

CHERRIES − Constructing Healthcare Environments through Responsible Research Innovation and Entrepreneurship Strategies − is an EU funded project aimed at testing RRI and demand-oriented approaches to inform and shape regional innovation policies and strategies (incl. e.g., Smart Specialisation Strategy − S3) to better meet the current challenges that healthcare innovation ecosystems are facing in Europe.

Responsible Research and Innovation (RRI) is a new framework for science proposed to researchers, scientists, and innovators. It can be described as a process sensitive towards expectations, needs, worries, and problems of society, where all societal actors work together during the whole Research & Innovation process in order to ensure the best possible outcomes. The notion of Responsible Innovation (RI) requires a form of governance that will direct or re-direct innovation towards societally desirable outcomes. RRI in health aims to advance the alignment between health needs, (bio)medical and health technology research, development of products and processes, and implementation in health practice by means of a systematic collaboration with all stakeholders involved.

In this context, CHERRIES is piloting a new RRI driven participatory approach to shape territorial R&I policies in the healthcare sector. In particular, it is aimed at enabling RRI policy experiments in healthcare in three European territories: Murcia (ES), Örebro (SE), and the Republic of Cyprus (CY). The CHERRIES experiments address opportunities and challenges associated with the role of "demand" at the crossroad of challenge-oriented, economy enhancing, and sector-specific policy-making within the healthcare sector, thereby addressing the EU Societal Challenge of "Health, demographic change and wellbeing". The project aims to create more open, inclusive, and self-sustaining R&I ecosystems by ensuring bottom-up involvement of all kinds of citizens, irrespective of their age, gender, ethnicity, and socio-economic background.

As shown in the Figure below, in CHERRIES the RRI framework is applied to mobilise territorial stakeholder ecosystems and engage them into regional pilot actions aimed at:

a) Identifying needs in the healthcare sector at the territorial level
b) Encourage the proposition and co-creation of innovative solutions to the needs identified
c) Stimulate institutional reflexive processes on how to innovate products and services in the healthcare sector through participatory approaches
d) Present evidence-based recommendations for revision of sectoral policies, strategies, and innovation support instruments.

In this framework, as part of the WP3 "Preparation of territorial frameworks for RRI-based experiments" of the CHERRIES Project, a task (Task 3.1 − Setting up of a toolbox for RRI experiments in the territorial healthcare sectors) is included, aimed at developing a Toolbox covering organisational and institutional aspects of RRI implementation processes in the healthcare context and at establishing a knowledge base for the RRI territorial experiments to be carried out in WP4 (Territorial demand-oriented policy experimentation).
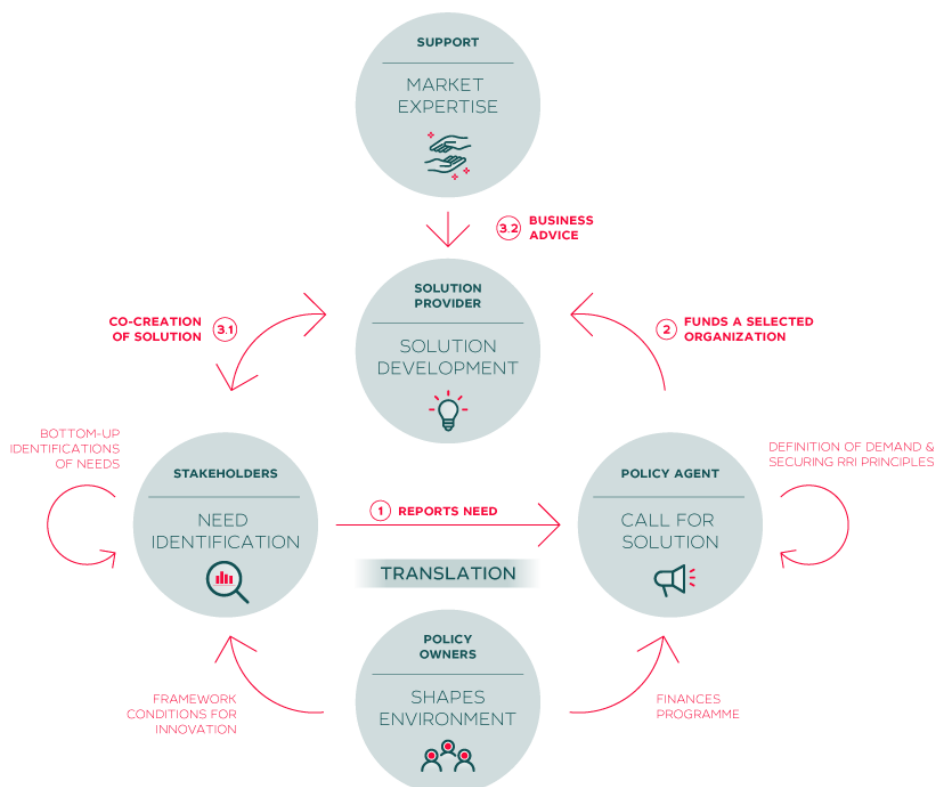
This deliverable (D3.1 − RRI & Experiment Toolbox), incorporates the main outcome of Task 3.1, namely the Toolbox itself. The structure, the contents, and the text of the present document (D3.1) coincide, therefore with the CHERRIES Toolbox which will be uploaded, as a web-tool, to the institutional website of the project, at the beginning of 2021 (within the section "Resources").

2. WHY THIS TOOLBOX AND TO WHOM IS IT FOR

The focus, in the CHERRIES project, is about the implementation of "territorial" RRI to tackle societal challenges in health through the establishment of territorial knowledge coalitions of key actors. These coalitions are committed to attain responsible innovation in health and to improve the governance of the innovation processes and policies in facing the huge transformations that are putting healthcare systems under pressure. In this framework the project has foreseen the application of RRI principles in the implementation of three regional pilots based on the demand-driven innovation approach for the identification of unmet needs in health and the co-creation of responsible innovation solutions to those needs.

To this end, the CHERRIES Toolbox is aimed at providing European territories with relevant resources and guidance on how to build and replicate RRI experiments in their healthcare ecosystems and to support the exploitation of results obtained in other European or national projects.

It is also aimed at facilitating a process of capacity building for territorial stakeholders preparing them for the entire co-creation process within the three regions. Finally, this toolbox might also be useful for the so-called "mirror" territories (i.e., the community of other regions in contact with CHERRIES project and interested in implementing a RRI demand-driven innovation approach in their regions) and for the next phases of the CHERRIES project.

The toolbox is conceived as an organised set of relevant resources useful for understanding and framing responsible innovation in health and for triggering a reflection on possible RRI Institutional pathways of change aimed at including innovative participatory approaches and RRI principles within the organisations engaged in the R&I healthcare system in the three regions.

It must be considered that during the last ten years, the European Commission promoted and funded hundreds of projects explicitly referring to the policy concept of Responsible Research and Innovation – RRI, its six key elements or "policy agendas" (ethics, gender, public engagement, education, open access, and governance), and its four dimensions (anticipation of possible impacts of the research outputs; reflexivity on the research activities; inclusiveness regarding the participation of all the concerned stakeholders; responsiveness with regards to societal needs and expectations). This effort was aimed at activating processes and creating spaces allowing societal actors (researchers, citizens, policymakers, business, third sector organisations, etc.) to jointly contribute to research and innovation activities and policies.

This 10-year engagement on RRI led to the establishment of a community of practices and the creation of a big stock of theoretical and practical knowledge (including experiences, methods, techniques, tested in different domains) on RRI. Therefore, for every RRI key, a large set of resources (toolkits, guidelines, reflexive tools, case studies, etc.) are already available.

The existence of comprehensive and consolidated RRI platforms[1] already established and developed during the last 10 years within the framework of European Projects was an important aspect considered for building the CHERRIES Toolbox, together with the screening of European projects and initiatives relevant with RRI in the healthcare domain (see section 3). So, during Task 3.1 a meta-analysis (i.e., a second-level analysis) of the several existing resources has been carried out (paying particular attention to those concerning the health sector) and the ones assessed as most useful and relevant in the context of the CHERRIES experiments, have been selected for inclusion in the toolbox.

The toolbox proposes methodologies, techniques, and tools related to RRI which can be used by different kinds of stakeholders (academia, SMEs and industries, civil society organisations, public administrations, etc.). The content of the Toolbox has been tailored taking into account its possible users. The toolbox is addressed to relevant actors of R&I healthcare systems interested in the design and implementation of Responsible Innovation pathways for the governance of the complex transformations affecting R&I in the healthcare sector.

In consideration of the CHERRIES aims, the main target groups of the Toolbox are the territorial partners involved in the RRI demand-driven innovation approach as well as the other relevant actors in the three regional ecosystems. They have been classified using the 4P model, which includes:

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[1] The most famous example is the RRI Tools Platform (https://rri-tools.eu).

− *Policymakers* → national, regional, local authorities establishing the context in which the healthcare system operates
− *Payers* → procurement actors, social security, private or public health insurance
− *Providers* → public or private healthcare service delivering/provision to patients, including professionals
− *Patients* → citizens, voters, taxpayers, care seekers, care recipient.

The CHERRIES approach provides for an interactive collaboration model among multiple stakeholder groups, throughout the process of design, implementing, and evaluating the experiments. These groups belong to three different categories of actors:

− Institutional healthcare actors (policymakers, payers, providers)
− Institutional Innovation actors (policymakers, funding bodies, RPOs, intermediary organisations)
− Non-Institutional actors (patients, healthcare professionals, innovative business).

The toolbox aimed to organise a pool of resources responding to the needs and expectations of both individual stakeholders and the healthcare local ecosystem as a whole. For this reason, within Part Two of the Toolbox, for each resource, its specific reference target group (target group that had in the past used the resources or that might take advantage in using it) is suggested.

The Toolbox' design process and the adopted criteria are described in the following chapter.

3. NATURE OF THIS TOOLBOX AND HOW THE TOOLBOX WAS BUILT

This chapter deals with: the building of the Toolbox; some basic choices shared with the CHERRIES partners on how to set up its final version, concerning, in particular, the criteria for the selection of the resources and the kind of resources included in the Toolbox; the nature of this toolbox as an "open" process.

3.1. The Toolbox design process

The design process of the Toolbox was articulated in the following five steps, partially overlapping:

STEP 1 – First round of screening and collection of relevant resources for CHERRIES (January-March 2020)
The first step for building the Toolbox was the screening and collection of existing RRI platforms, European projects, and initiatives known by the Consortium partners, aimed at the identification of relevant resources on RRI in health and on the demand-driven innovation approach in CHERRIES.

STEP 2 – Analysis and classification of the resources identified and establishment of an internal knowledge repository (March-April 2020)
The resources gathered were analysed and classified within a preliminary taxonomy suggested for the establishment of a knowledge repository for internal use in the CHERRIES Consortium, aimed at supporting the process of capacity building for the territorial partners in view of the design of the regional RRI / demand-driven experiments.

STEP 3 – Second round of identification and analysis of relevant resources (May-November 2020)
After the establishment of the internal knowledge repository, the K&I team continued to select documents and resources to be included in the Toolbox, by desk research work, networking activities, and exchanges with RRI territorial or innovation in health projects or co-creation in health initiatives and further interaction with CHERRIES partners.

STEP 4 – Sharing with the CHERRIES partners basic choices for the articulation of the Toolbox (June-October 2020)
Through several exchanges with the CHERRIES partners, the K&I team reflected on the best way to set up the Toolbox taking into account the relevant resources identified and analysed. The aim was to tailor its structure and contents to the needs of territorial partners and stakeholders. The discussion, and sharing, of basic choices for the setup of the Toolbox was finalized in October, through the set-up of a concept note prepared by K&I and shared with the Consortium partners and through the implementation of focused working meetings.

STEP 5 – Final selection of resources, definition of sub-categories, drafting of the deliverable 3.1 (October-December 2020)
During this period, the final choice of the resources to insert in the toolbox was done. It was also formulated the final proposal to articulate the selected resources within five categories, each one with its sub-categories. Finally, the present Deliverable was drafted.

3.2. The setting up of the Toolbox

As stated in the Description of Work, the development of the Toolbox required some basic choices – i.e., some strategic orientation on how the toolbox might be set up – needed for selecting and arranging the resources and ultimately defining its nature. Among these choices (shared with the CHERRIES partners) there were those concerning:

 − The criteria for selecting the collected resources
 − The kind of resources to be included in the Toolbox.

The selection of the resources was based on four main criteria:

Content relevance
The first criterion adopted was the relevance of the resource with respect to one or more steps required for applying the RRI innovation demand-driven approach – i.e., the CHERRIES Model – that will be tested during the three experiments.

Sectoral relevance

The second criterion was the relevance of the resource to the healthcare domain – i.e., research and innovation in healthcare. Obviously, this does not mean that resources not addressing healthcare-related issues were automatically discarded. Rather, this criterion was also used for selecting resources unrelated to the healthcare sector, but which were considered relevant to it (for example, because dealing with issues crosscutting different sectors or proposing solutions that could be usefully applied also in the healthcare sector).

Quality

The third criterion applied for the selection was the quality of the resource. This included, e.g., the reliability, clarity, completeness, and innovativeness of its contents as well as the actual transferability of the solutions it proposed.

Year of Publication

The fourth criterion adopted concerned the year of publication. Considering the rapid changes affecting the healthcare sector, resources published in the last ten years have been preferably selected. This is also the period in which the policy concept of RRI has been formulated, disseminated, and promoted through projects and measures. Some exceptions have been made when the resource was particularly important according to the other three criteria.

The Toolbox includes different kinds of resources, such as:
- Documents (guidelines, handbooks, reports, articles, etc.)
- Tools (grids, forms, training materials, etc.)
- Platforms (self-reflexive tools, repositories, etc.)
- Online and audio/video materials (webinars, tutorials, interviews, etc.).

The toolbox incorporates existing resources from European and national projects and activities focusing on RRI, RIS3, and healthcare interface. Local and regional initiatives were also taken into consideration.

The Toolbox also contains documents and resources produced by the CHERRIES project at this stage of the process (mapping exercise, call for needs/demand identification, call for solutions, etc.) of the implementation of the experiments.

3.3. The Toolbox as an outcome of an open process

Considering that RRI is a context-sensitive concept and that the CHERRIES experiments are an open process still on-going, it is worth noting that, even though a significant number of relevant resources on RRI in the healthcare sector and on the demand-driven and co-creation approach for innovation in health was achieved, this Toolbox is far for being exhaustive. Moreover, it cannot provide easy or "ready-made solutions" for the replication of the CHERRIES methodology and the implementation of RRI institutional change pathways within different regional R&I healthcare ecosystems. What this Toolbox can offer to its readers is a guided selection of inspiring resources and tools which might help to foster a reflection on how to replicate, and consequently tailor solutions and tools within different institutional and regional contexts.

The Toolbox, in fact, was set up for supporting a process of institutional reflection and capacity building on RRI in health for the key territorial actors of the R&I healthcare system involved in the territorial experiments. It is worth highlighting that this process, started during the preparation stage, will go ahead during the entire CHERRIES project. To this end, the tailoring, testing, and adoption of some of the resources, tools, methodologies provided in this toolbox during the implementation of the three territorial experiments, might constitute, in turn, during the next stages of the implementation of the CHERRIES Project, the further source for the improvement/enrichment of this Toolbox.

Therefore, the Toolbox should be considered the outcome of an open process, based on the results of the three experiments and the experiences of partners and stakeholders. For these reasons, other resources or new categories might be incorporated in the Toolbox in consideration of the actual implementation of the CHERRIES activities within the three regions. Furthermore, other relevant resources and new tools of interest might be identified from the implementation of several on-going EU projects focused on the "territorial" dimension of RRI (SWAFS 14 ecosystem) and eventually incorporated.

4. HOW TO EXPLORE/USE THE TOOLBOX

In this chapter the structure of the Toolbox is illustrated, with an explanation of how the resources are presented within the different parts of the Toolbox.

4.1 The structure of the Toolbox

As a result of the itinerary illustrated above (point 3.1), the Toolbox was articulate in this present Introduction and two main parts:

− The first part − RRI in health. General Resources for understanding and framing RRI in the healthcare sector
− The second part − RRI demand-driven innovation approach.

In **Part One** of the Toolbox can be found a brief introduction and some useful resources for interpreting and framing the concepts of RRI, Open Science, Open Innovation, and territorial RRI in general and in the health domain. These resources are suggested for supporting a reflection about what's at stake with RRI, why RRI changes should be put in place, and what this might mean for the governance of the R&I healthcare sector.

Obviously, in the spirit of this Toolbox, only a few selected more theoretical resources are here presented. These resources were considered of particular interest for a process of interpretation, which represents a preliminary step in view of the formulation and implementation of a project of change.

In particular, this part is aimed at providing basic information and references about RRI with a focus on:

- Healthcare sector
- General resources for the interpretation of "territorial RRI" as a result of the integration between RRI principles and regional innovation policies (like the Smart Specialisation Strategy)
- Relevant (theoretical and methodological) contributes to framing sustainable/responsible Innovation in Health, with particular reference to the RRI process dimensions
- Examples of projects, initiatives, or inspiring readings on RRI in Health, in which there is a focus of RRI.

This part is organised in the following three short chapters:

1. A new framework for science and society
2. Trends in the healthcare sector and healthcare R&I system
3. An introduction to Responsible Research and Innovation.

Part Two of the Toolbox is organised according to the basic elements of the RRI demand-driven innovation approach of CHERRIES – i.e., the model adopted in the three pilot experiments – aimed at promoting more responsible, inclusive, and sustainable healthcare ecosystems and at activating RRI-oriented transformation processes in the organisations involved at the local level and beyond. Such a model has a processual nature that entails in every step the active engagement of stakeholders in a co-creation effort.

To this end, this part of the Toolbox is arranged in 5 sections (coincident in some way with the steps of the CHERRIES model) within which all the collected resources have been sorted.

These 5 sections representing five specific categories (each one split into 3 to 5 subcategories) are the following:

a. Framing [and setting] the scene for RRI and demand-driven innovation pilots in health
b. Making the process of needs identification in health more open, inclusive, and responsive to territorial/societal challenges
c. Co-creation for the inclusion of social values in the design, development, and test of responsible innovation solutions in health
d. Adoption, implementation, and deployment of innovation solutions
e. Establishing practices and methods for evaluation.

4.2. How to explore the Toolbox

As said above, **Part One** of the Toolbox is structured in three sections. Within each section, some selected resources are provided within the text (accessible through an hyperlink), in some endnotes or within specific boxes

Part Two is organised differently from the previous one. In this part, the resources are arranged according to the 5 categories illustrated above (and within each category in thematic subcategories). In this second part, after a general short introduction in which the CHERRIES methodology is recalled, each section is introduced by a short rationale that illustrates the contents of each category, even with some examples. Each section is articulated from a minimum of three to a maximum of five thematic subcategories, each introduced by a short presentation and followed by the list of the relevant resources. Here, the resources are directly accessible (with a hyperlink) from the main text. When available, some resources produced directly within the CHERRIES project are included in the section.

Within each sub-category, every resource is described according to the form adopted for the preliminary knowledge repository set up during the first stage of the project. For each resource, the following information is provided:

- Progressive identification number of the resource
- Title of the resource
- Short description of the resource
- Part of interest of the document
- Target groups
- Link (Hyperlink) for accessing the resource.

Overall, this second part of the Toolbox contains 213 resources. As some of these resources have been used for more than one section, the progressive number of individual resources is 241. In few cases the resources are not provided with a direct link, but they will be available on request to the CHERRIES team.

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 challenges[2].

However, orienting and managing innovation processes can be problematic. The scientific and technological breakthroughs which are transforming the future of medicine and health inevitably

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[2] See: Larisch, L. M., Amer-Wåhlin, I., & Hidefjäll, 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.

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.

Examples of trends, partially overlapped, occurring at the crossroad between science, innovation, and health are mentioned below[3].

− **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 issuer 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 health-care 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 patienships".

− **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).

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[3] 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.

− **User-driven innovation.** This trend has to do with the growing tendency also in health-related innovation to <u>tailor new products and services to users' needs</u>, recognising then a proactive role in the innovation process.

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

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)[4]".

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)[5]".

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[4] Consoli, D., & Mina, A. (2009). An evolutionary perspective on health innovation systems. *Journal of Evolutionary Economics*, *19*(2), 297–319.
[5] 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)[6]."

"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 approaches[7]."

"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; Inclusive[8]."

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

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

[7] 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

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

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).

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 responsibility[9]".

– **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.

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

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 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.

These process dimensions mean
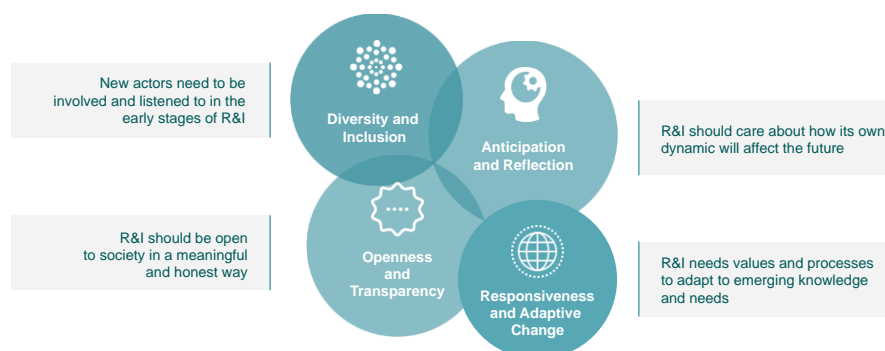
New actors need to be involved and listened to in the early stages of R&I

Diversity and Inclusion

Anticipation and Reflection

R&I should care about how its own dynamic will affect the future

R&I should be open to society in a meaningful and honest way

Openness and Transparency

Responsiveness and Adaptive Change

R&I needs values and processes to adapt to emerging knowledge and needs

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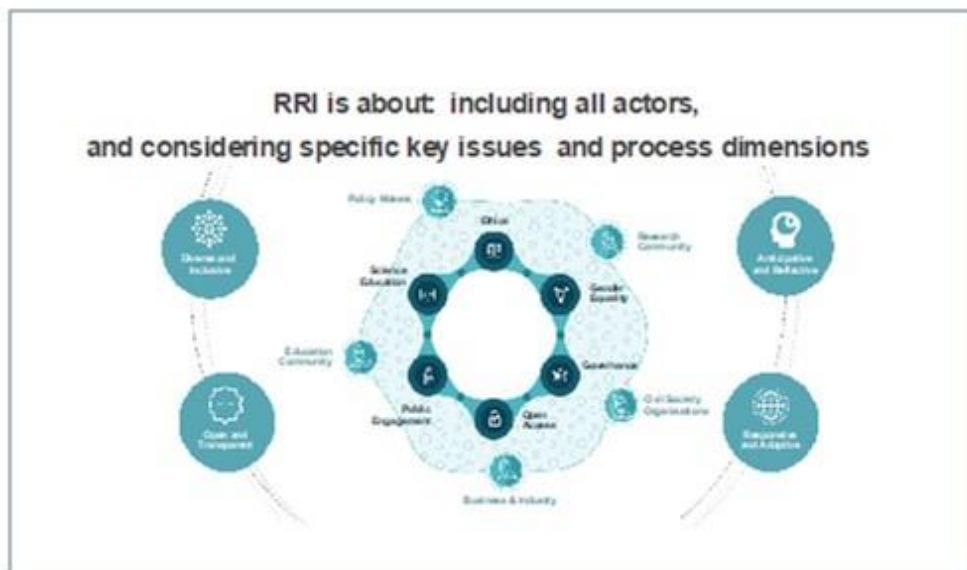
Source: A Practical Guide to Responsible Research and Innovation: Key Lessons from RRI Tools, 2016

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)[10]. EU Regions are starting recently to address RRI and they are facing common challenges in the understanding and implementation of this approach at territorial level[11].

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. Fitjar[12], 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 responsible for their territory, thus facing the factors leading to de-territorialisation (i.e., a

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[10] "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
[11] 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
[12] 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.

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 or 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 Starbios 2 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 COVID19 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 resources[13]. 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 innovations[14]. 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.

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[13] 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.
[14] 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 way[15]".

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 world[16]".

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.

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[15] 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.
[16] Silva, H. P., Lehoux, P., Miller, F. A., & Denis, J. L. (2018). Op. Cit.
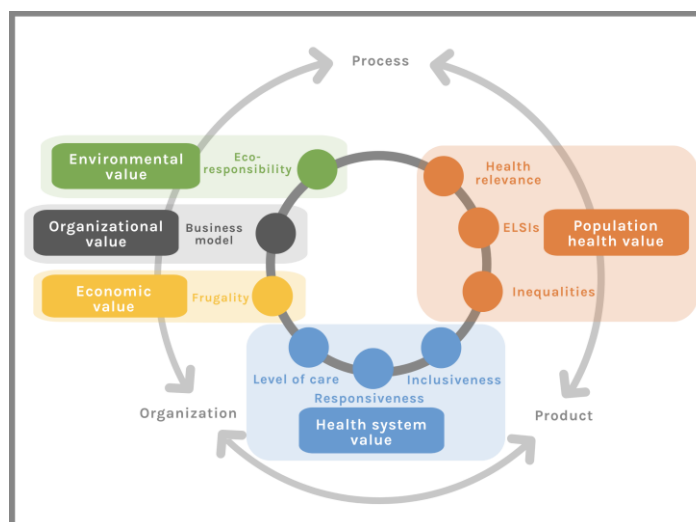
Source: InFieri Project, 2020

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)

PART TWO
RRI DEMAND-DRIVEN INNOVATION APPROACH

Inspiring readings, tools, promising practices for the implementation of the CHERRIES methodology

This part of the Toolbox provides resources useful for implementing RRI-oriented demand-driven innovation initiatives in healthcare and for triggering related-process of structural change within R&I territorial healthcare ecosystems. It is organised according to the basic elements of the RRI demand-driven innovation approach of CHERRIES – i.e., the model adopted in the three pilot experiments and described in the Deliverable D3.2[17] – aimed at promoting more responsible, inclusive, and sustainable healthcare ecosystems and at activating RRI-oriented transformation processes in the organizations involved at the local level and beyond. Such a model has a processual nature that entails in every step the active engagement of stakeholders in a co-creation effort.

Therefore, these resources are arranged within five sections, coincident in some way with the steps of the CHERRIES model. Each section covers different dimensions related to the preparation and the activation of the process, the implementation (and the sustainability) of the pilots, the evaluation and self-reflection of the process of change.

− **SECTION A** – Framing (and setting) the scene for RRI and demand-driven innovation pilots in health*, articulated in 4 subcategories:
     1. *Mapping territorial ecosystem*
     2. *Actors' mapping and analysis*
     3. *Partnerships and territorial coalitions*
     4. *How to start the process.*

− **SECTION B** – Making the process of need identification in health more open, inclusive, and responsive to territorial/societal challenges organised in 3 subcategories:
     1. *Demand-driven and user-led/people-centric/open innovation approaches in healthcare*
     2. *Participatory approaches and methods for patients and stakeholders engagement for research agenda setting in health*
     3. *Call for needs, Call for challenges, Open Innovation Calls in health.*

− **SECTION C** – Co-creation for the inclusion of social value in design, development, and test of responsible Innovation solutions in health sorted within 5 sub-categories:
     1. *Call for solution for addressing needs and challenges*
     2. *The engagement of patients, citizens, and public in innovation and research*
     3. *Engagement and mobilisation of stakeholders in research and innovation activities*
     4. *Co-creation of the solution*
     5. *Legal, Ethical and Privacy requirements in co-creation research and innovation.*

− **SECTION D** – Adoption, Implementation, and Deployment of Innovation Solutions articulated in 4 subcategories:
     1. *Solution Implementation*
     2. *RRI and Responsible Innovation in practice*
     3. *Pre-commercial procurement: a possible way for innovation to market access*
     4. *Commercialisation.*

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[17] CHERRIES Deliverable D3.2 "Adapted territorial methodology for the experimentation per territory"

- **Section E** – Establishing practices and methods for evaluation arranged in 3 subcategories:
    1. *Assessment of the embedment of RRI;*
    2. *Assessment of Gender equality in organizations*
    3. *Impact assessment and sustainability.*

Each section is introduced by a short rationale aimed at framing the key issue, the kind of resources included in all the sections, and the subcategories in which the section is articulated. Within each subcategory, a brief introduction is furthermore provided, followed by the list of the resources with their description and related link for accessing it.

A. FRAMING [AND SETTING] THE SCENE FOR RRI AND DEMAND-DRIVEN INNOVATION PILOTS IN HEALTH

CHERRIES Project aims at improving the framework conditions for responsible healthcare innovations. Before intervening in such complex systems of general economic and domain-specific policies one must take stock of what is already out there, what is working well and what could hinder the proper operation of such systems. The challenge CHERRIES is facing is to integrate into one analytical framework the innovation outputs (product, service, organisational, social innovations), subsystems (preventive, promotive, therapeutic, assistive care) and sources of innovation needs (patients, practitioners, payers, and policymakers). Such a framework will allow to identify actor constellations, innovation dynamics, knowledge bases, innovation modes, and the like.

For this reason, the first category of the Toolbox contains resources useful to frame the scene for RRI and demand-driven innovation pilots in healthcare by mapping the regional innovation systems and learning about regional specifics as a first step for transforming healthcare innovation policy instruments to foster responsible and problem-oriented healthcare policies and practices.

This mapping exercise is also instrumental in pursuing another important element of CHERRIES approach i.e., that of activating a process of change towards a more open, inclusive, and responsive innovation ecosystem in health, by embedding RRI in healthcare. Indeed, implementing Responsible Research and Innovation, which is a context-dependent process, requires mapping and analysis of any given ecosystem, which is a complex system including actors and stakeholders, infrastructures, policies, resources, innovation and RRI practices, trends, and drivers and obstacles.

In this sense, another element to keep in mind is related to the conditions and requirements for a group of organisations to act for promoting and implementing a participatory process of change, requiring the engagement of different stakeholders, including citizens. In fact, in the entire RRI demand-driven innovation approach, stakeholders and partnerships/coalitions of different local actors play a very important role in each step of its implementation. Starting the process of embedding RRI in organisations or in ecosystems requires the establishment and the activation of partnerships and coalitions of actors in core teams, able to steer the process. For this reason, the category includes specific resources on framing the scene, on stakeholders mapping and analysis, on public/private partnerships and territorial coalitions, and on requirements and ways to start a process of change.

Therefore, the resources collected in this category have been grouped into the following four subcategories:

A.1. Mapping territorial ecosystem
A.2. Actors' mapping and analysis
A.3. Partnerships and territorial coalitions
A.4. How to start the process.

A.1. Mapping territorial ecosystem

In implementing the RRI demand-driven approach, mapping the territorial ecosystem represents the first step. The mapping is aimed at providing a vision of the context, allowing the identification of priorities, needs, and challenges to which the three CHERRIES pilots have to provide a solution. A territorial ecosystem includes different elements, also depending on the issues addressed, such as infrastructures, actors, and stakeholders (see next subcategory), programs, policies (and in particular innovation policies, healthcare policies, regional innovation policies such as the Smart Specialisation Strategy, Responsible Research and Innovation policies, and the like).

This subcategory contains resources on how to carry out the mapping of a given ecosystem. Such an exercise requires to identify, collect, and analyse, with different approaches, data, documents, and information on some elements as, for example: social, economic, demographic, environmental, health trends; regional base indicators on these trends; data on the research and innovation local/regional systems (for example, data on publications, patents, R&D projects, number of scientific and technological organisations, etc); active and relevant policies (on innovation, on healthcare, on RRI, etc.); good or innovative practices in healthcare; infrastructures; obstacles, facilitating and hindering factors; priorities; actors, stakeholders, active partnerships and territorial coalitions; etc. In order to identify and record some of these items, the involvement of stakeholders might be required by means of interviews, focus groups, workshops, etc.

Some resources have been prepared and used in the context of European projects focused on territorial governance or co-creation approaches and described in deliverables and reports (such as TeRRItoria, SeeRRI, Siscode, etc.). Other resources describe the mapping exercises carried out in the framework of empirical studies or reflections. Some resources are focused on the Smart Specialisation Strategy (its assessment, implementation and its possible integration with RRI). Finally, other resources provide suggestions about possible sources to be considered when mapping a given ecosystem, like country reports, national and official studies, platforms, etc.

In CHERRIES the territorial mapping of the three regions of Murcia (Spain), Örebro (Sweden), and Cyprus includes some of the elements mentioned above. The territorial context has been described on the basis of three elements: territorial healthcare structures and priorities; stakeholder groups and societal actors; policy frameworks & instruments for innovation support systems on three policy issues (RRI, Smart Specialisation Strategy, and healthcare). In particular, CHERRIES carried out two interconnected actions in mapping the territories: one action was focused on innovation territorial policies and in particular on the Smart Specialisation Strategy and the other was geared towards mapping stakeholders and policy ecosystem and their relationships. In CHERRIES the mapping activity is being complemented with a study on innovation biographies of health pilots and with a reflection on territorial RRI implementation and future potential in healthcare.

Here below are reported the resources for mapping territorial ecosystems.

1. Regional innovation ecosystems for healthcare

The fourth episode of the "CHERRIES webinar series 2020 Exploring responsible healthcare ecosystems in Europe" was devoted to a reflection on "Regional innovation ecosystems for healthcare", with the contribution of Gaston Heimeriks (Leiden and Utrecht University) and Anett Ruszanov (ERRIN). In particular, the webinar provides an important occasion to reflect on the possible integration of RRI with Regional Innovation Smart Specialisation Strategies (RIS3) and how European Regions leverage their diversities to boost innovation.

Part of interest: The entire webinar

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

2. CHERRIES Guidelines for territorial mapping

These are the Guidelines for territorial mapping, drafted and used by CHERRIES (Deliverable D2.1) for framing the scene of the three territorial ecosystems of Örebro (Sweden), Murcia (Spain), and Cyprus (2020). Mapping policies (on innovation and research, on healthcare, on Smart Specialisation Strategies, etc) and stakeholders are of vital interest for the preparation of the three pilots. The purpose of the document is to guide territorial partners through the territorial mapping exercise in a straightforward manner. The three main sections addressed in the guidelines, namely Stakeholders' identification and prioritisation, Gathering and screening policy instruments and strategies, and Research and Innovation Strategies for Smart Specialisation Framework, are indeed conceptually and in practical terms connected. The document describes steps by step the implementation of this complex mapping exercise. The methodology used a mixed-method ranging from desk research, expert interviews to bibliometrics indicators and networks.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

3. Report of the mapping of the three ecosystems of Örebro, Murcia and Cyprus

The resource is the Synthesis of mapping territorial R&I healthcare ecosystems involved in the three pilots of CHERRIES IN Örebro (Sweden), Murcia (Spain), and Cyprus.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

4. Methodological guidelines for active mapping

The document (See SeeRRI Project, Deliverable D2.1, 2019) describes the quantitative and qualitative procedures implemented for mapping the R&I stakeholder ecosystems, aimed at including RRI in regional policies. The quantitative methodology consists of the identification of the R&I actors that are mostly active in regional research projects within the R&I ecosystems, by analysing existing R&I databases (i.e., EUPRO, PATSTAT), and then by using a 'Quantitative Data Collection Form'. The qualitative methodology consists of the qualitative evaluation of the RRI state-of-the-art into the regional development policies and tools.

Part of interest: See in particular Chapter 2 "Methodological guidelines for mapping R&I ecosystems" and the two annexes.

Target groups: Policymakers, RPOs, Innovation business, Higher Education institutions, Intermediaries, CSOs, Funding organisations

→ **Link to the document**

5. Set of mapping tools

The document (TeRRItoria Project, Deliverable D2.1, 2019) contains indications and tools applied for mapping the territorial ecosystems of the five experiments of territorial RRI of the project. It describes the methodology and criteria adopted. It also gives a good overview of how to use observation grids and shows results achieved by using this grid technique.

Part of interest: The entire document, and in particular, Pp. 9-23 showing the methodology, observation grids and which questions to ask about stakeholders during the mapping process.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

6. Map of the territorial *milieux*

In the framework of the TeRRitoria project (Deliverable D2.2, 2019) a Map of Territorial *Milieux* has been developed. It contains the mapping outcomes of key societal *milieu* stakeholders; RRI-oriented or compatible practices and initiatives; the main "territorial policies" developed by actors at different levels of governance. The map also contains examples of "territorial factors", i.e., social, economic, demographic and cultural risks and emerging opportunities for each of the considered territories.

Part of interest: The part of interest (Pp. 8-37) includes the summary reports of the five experiments.

Target groups: Policymakers, RPOs, Innovation business, Higher Education institutions, Intermediaries, CSOs, Funding organisations

→ **Link to the document**

7. Toolbox for co-creation journey

The SISCODE Toolbox aims to facilitate the design and implementation of co-creation journeys for the SISCODE laboratories, focussing on better understanding and prioritisation of the particularities of each context. Context analysis is the first and crucial starting point of co-creation and action. In particular, on this aspect, the SISCODE Toolbox contains tools and resources on how to define the challenge, the lab capabilities, and the policy environment.

Part of interest: In particular, see the section "Analyse the context".

Target groups: RPOs, CSOs, Innovation Business, Policymakers, CSOs

→ **Link to the document**

8. Mapping innovation priorities and specialisation patterns in Europe

The document (Sörvik, & Kleibrink, 2015) gives a guideline on how to approach the mapping of innovation priorities and specialisation patterns in Europe. It is also helpful for promoting collaborations among regions. The mapping exercise is based on Eye@RIS3, an interactive open data tool that gives an overview of the envisaged RIS3 priorities of regions and countries in Europe.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Innovation Business

→ **Link to the document**

9. Inventory of RRI governance innovation practices

This document (TeRRItoria Project, Deliverable D3.2, 2019) is an inventory of 43 RRI Governance Innovation Practices detected in RRI projects conducted in Europe and beyond, proposing relevant and new models of RRI governance innovation practices. Four of the examined projects are dealing with healthcare issues. Many projects include an ecosystem mapping exercise functional to RRI implementation using different approaches, requiring also different levels of stakeholder engagement. One of these projects is FoTRRIS whose context mapping work is described. In particular, FoTRRIS carried out the context mapping exercise by the implementation of working groups, described, among other things, in the inventory. Another interesting project is the Interreg MARIE focused on the integration of RRI into the Smart Specialisation Strategy in 8 European regions.

Part of interest: See in particular Part 4.6, Pp. 74-88 devoted to FoTRRIS; and the part 4.11 Pp. 131-137 devoted to MARIE. See also parts 4.7 on INHERIT project on health and environment; 4.9 on Responsible Industry project on RRI in the industry; 4.11 on MARIE Interreg project on RRI and RIS3; and 4.15 EnRICH project on RRI education.

Target groups: Policymakers, Providers, Professional, Patients and civil society, RPOs, Innovative business, intermediaries

→ **Link to the document**

10. Understanding healthcare innovation systems: the Stockholm Region case

The paper (by Larisch, Amer-Wåhlin, and Hidefjäll, 2016) contains a new method (functional dynamics approach) for analysing the wider socio-economic context and conditions for innovation processes addressing healthcare challenges in the Stockholm Region, using the functional dynamics approach to innovation systems (ISs). The analysis is based on triangulation using data from 16 in-depth interviews, two workshops, and additional documents. The analysis revealed several mechanisms blocking innovation processes such as fragmentation, lack of clear leadership, as well as insufficient involvement of patients and healthcare professionals. Furthermore, restrictive rules for collaboration with industry, reimbursement, and procurement mechanisms limit entrepreneurial experimentation, commercialisation, and the spread of innovations.

Part of interest: The entire article (and in particular the figures).

Target groups: Policymakers, Providers, Patients, Payers, Innovation Business, RPOs, Higher Education Institute

→ **Link to the document**

11. Roadmaps for up-scaling. Possible pathways to patient-centred, holistic care for RD Patients and patients with complex needs in Austria, Romania and Spain

The resource is an INNOVCARE project document (Deliverable D9.4, 2018). Scaling up refers to identifying opportunities and barriers at broad institutional scales, with the goal of changing the system that created the social problem. The report discusses possible ways to up-scale elements of integrated, person-centred, and holistic care for people with complex and/or rare conditions to other member states and other regions. The roadmaps focus on potential priority areas as well as possible next steps that can be taken towards holistic care models, improving the care situation for patients. The document describes the implementation of care holistic approach Road map in Spain, Austria, and Romania at macro, meso, and micro levels. The identification of priorities of the territories at the three levels was made also by interviews with stakeholders and expert workshops.

Part of interest: Pp. 1-8 about road mapping.

Target groups: Policymakers, Providers, Professionals, Patients, CSOs, RPOs, Innovative business

→ **Link to the document**

12. Re-engineering the Cypriot healthcare service system

Cyprus is undergoing a major reform, namely the introduction of primary care driven national healthcare system. The aim of the present study (by Pallari, Samoutis, Rudd, 2020) was to assess the existing state of training, support, quality, guidelines, and infrastructure towards a better healthcare system in Cyprus. This is a mixed-methods study combining statistical data until October 2016 and workshop discussions delivered in Cyprus in November 2015.

Part of interest: The entire article.

Target groups: Policymakers, Providers, Professionals

→ **Link to the document**

13. Spain. Health System review

The document (WHO, European Observatory on Health Systems and Policies, Bernal-Delgado et al., 2018) analyses the Spanish health system taking into account recent developments in organisation and governance, health financing, health care provision, health reforms and health system performance, healthcare challenges (for example related to lifestyle and obesity). It contains also data and indicators.

Part of interest: The entire document.

Target groups: Policymakers, Providers

→ **Link to the document**

14. State of Health in the EU. Country profile

This is a portal of EC, OECD, and European Observatory providing country reports on Health systems and policies updated in 2019. Each country report contains: the list of the highlights on health issues ; basic data on Health; the risk factors; some data and reflections about the performance of the health system (effectiveness, accessibility, resilience), and finally the key findings.

Part of interest: To be selected for the country of interest.

Target groups: Policymakers, Providers

→ **Link to the document**

A.2. Stakeholders' mapping and analysis

This subcategory contains some resources specifically focused on mapping and analysis of stakeholders (that might be individual or collective entities), an exercise that represents a first step in the more complex stakeholder engagement process (see also category C.). The aim of the analysis is to provide information, on the basis of a classification of stakeholders with respect to different elements, such as their interests, influence, and power, readiness to be involved, resources, competencies, links to networks, etc. This information is useful to prioritize the stakeholders and to define a tailored strategy of involvement for each of them in the pilot or in the project. The classification allows the promoter of the pilot/project/initiative to identify for each of them different levels of involvement. The stakeholder identification and mapping might be made following different approaches. Some approaches foresee also the organisation of workshops specifically devoted to stakeholder identification and analysis.

The resources of this subcategory, based on different approaches, have been set up by other projects, international organisations, universities, organisations active in the field of management.

In CHERRIES stakeholder mapping and identification was one important element of the context analysis (see also the subcategory A1), which contains also the classification of stakeholders on the basis of the four P model (Policymakers, Providers, Patients, and Payers). The CHERRIES stakeholder analysis within the mapping ecosystem is described in the Guideline for territorial mapping (Deliverable D2.1), while the three maps of the three ecosystems are contained in Deliverable D2.2. Furthermore, a tool for stakeholder analysis has been set up in preparation for the training workshop.

What follows are the resources of this subcategory.

15. Tool for stakeholder identification and involvement in training activities

This is the stakeholder identification and involvement tool set up by CHERRIES for the stakeholder identification and analysis for the Training Workshops (Task 3.2) carried out in preparing and accompanying the process of need identification and Calls for solutions. It is suggested to use the tool by the involvement of the local territorial partners in a meeting. The tool can be very helpful not only for the identification of the stakeholders to be involved in the territorial RRI Training Workshops but also during the different phases of implementation of the pilots (co-design and preparation, implementation, sustainability, evaluation). The tool can be used for defining influence, relevance, interests, and involvement strategy for each identified stakeholder.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

16. Stakeholder Analysis Guidelines

The document presents the Guidelines on how to perform a stakeholder analysis (by Schmeer, 1999). Stakeholder analysis is a process of systematically gathering and analysing qualitative information to determine whose interests should be taken into account when developing and/or implementing a policy or program. The Guidelines describe the 8 steps needed for stakeholder analysis.

Part of interest: The entire document

Target groups: Policymakers, CSOs, RPOs, Payers, Innovation Business, Providers

→ **Link to the document**

17. WHO Stakeholder mapping

This is a short guide of the World Health Organisation aimed at mapping potential key stakeholders in reproductive health and family planning service delivery. The guide describes the four steps of stakeholder mapping: identify stakeholders; analyse stakeholders; map relationships; prioritize the level of engagement.

Part of interest: The entire document.

Target groups: Policymakers, CSOs, RPOs, Higher education institutions, Providers, Professionals, Payers, Intermediaries

→ **Link to the document**

18. Public-Private Dialogue – Stakeholder mapping toolkit

PPD Public-Private Dialogue is a structured engagement among an inclusive group of relevant and local stakeholders that seeks to identify, prioritise, and recommend consensus as well as fact-based based solutions to a specific need, challenge, or problem. PPDs go well beyond standard stakeholder consultation or a simple exchange of opinion. The Guide has been prepared by the World Bank with the involvement of PPD practitioners to provide them with an option for stakeholder mapping by adapting a Network Mapping (NM) method and allow them to design dialogue platform and determine the participants at the concept stage; promote dialogue, ensure that the right people are invited in the dialogue; facilitate the dialogue among different partners of the dialogue. Three are the steps in stakeholder mapping: identify the purpose of the mapping; doing stakeholder mapping using the NMmethod; stakeholder analysis. The NM method has 6 steps: frame the right question, identify the actors involved; work through the links; determine motivations, discuss levels of influence; harvest observation and possible actions. The document contains also examples of applications.

Part of interest: The entire document.

Target groups: Policymakers, CSOs, RPOs, Higher education institutions, Providers, Payers

→ **Link to the document**

19. Stakeholder Analysis Matrix

This Stakeholder analysis matrix was set up by www.tools4dev.org a repository of tools to be used and adapted to different projects and initiatives. The matrix allows to collect, for each stakeholder, information about impact, influence, what is important for the stakeholder, how the stakeholders contribute to the project, how could the stakeholder block the project; and the strategy for engaging.

Part of interest: The entire document.

Target groups: Policymakers, CSOs, RPOs, Higher education institutions, Providers, Payers, Intermediaries

→ **Link to the document**

20. DFID – Tools for development – A handbook for those engaged in development activity

The Handbook includes a chapter on stakeholder analysis: why do it, which are risks and pitfalls. The Handbook suggests how to do stakeholder analysis using a workshop. The guide contains also tools and a matrix that might be used for stakeholder mapping and analysis.

Part of interest: Part 2 on stakeholder analysis.

Target groups: Policymakers, RPOs, Higher education institutions, Providers, Innovation business, Payers, Intermediaries

→ **Link to the document**

21. Manchester Metropolitan University, Stakeholder analysis toolkit

This toolkit contains information on: why and how to carry out stakeholder analysis in small, medium, and big project initiatives. It contains also suggestions on a possible strategy of stakeholders' involvement, taking into account their capacity of supporting or opposing the project. The toolkit provides examples related to university initiatives.

Part of interest: The entire document.

Target groups: Higher education institutions, RPOs, Policymakers, CSOs

→ **Link to the document**

22. SDCL&N Stakeholder analysis and mapping

This short document provides indications on what and what for stakeholder analysis and mapping; who are the stakeholders; the benefits of stakeholder analysis and mapping and how to do it. In particular, it describes the 7 steps for doing stakeholder mapping and analysis.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, CSOs, Higher education institutions, Innovation business, Providers, Payers, Intermediaries

→ **Link to the document**

23. Stakeholder matrix of Department of Health of Tasmania

This is the Stakeholder matrix to be used for the stakeholder analysis for developing a useful engagement plan. The matrix has been drafted and used by the Department of Health and Human Service of Tasmania.

Part of interest: The entire document.

Target groups: Policymakers, Providers, Patients, CSOs, RPOs

→ **Link to the document**

24. Engagement strategy & documentation of events

The document (Made4You Project, Deliverable D1.1, 2019) shows the stakeholder mapping process that Careables project has undertaken as well as its detailed stakeholder engagement strategies. Two elements are interesting of this resource: the need to identify and describe the community to engage; and the need to distinguish between individual and collective stakeholders. The resource describes different methods of engagement.

Part of interest: In particular Pp. 5-21.

Target groups: Providers, Professionals, Patients, and CSOs

→ **Link to the document**

25. Mapping stakeholders and policies in response to deliberate biological events

The article (by Katz, R. et al., 2018) provides an overview of policies triggered by Deliberate Biological Events (DBE) and gives a methodology to map policies (and stakeholders) in response to DBE, that use for visualisation a web-based tool.

Part of interest: The entire article.

Target groups: RPOs, Policymakers

→ **Link to the document**

26. Guidelines for the implementation of the Stakeholder Participation Process

This source provides Guidelines on the implementation of the stakeholder participation process, by defining the principles, the reasons and the forms of stakeholder involvement. The Guidelines have been used in MINATURA project aimed at stakeholder involvement in the preservation of mineral resources. The Guidelines describes also the process of stakeholder mapping and identification.

Part of interest: See for stakeholder identification, Pp.22-26.

Target groups: Policymakers, CSOs, RPOs, Innovation business, intermediaries

→ **Link to the document**

26. Global Mental Health Policy Influence Toolkit

This toolkit (created in 2015 in response to a report titled 'Global Mental Health from a Policy Perspective: A Context Analysis' made by the Research and Policy in Development (RAPID) team at the Overseas Development Institute ODI) was developed for the Grand Challenges Canada (GCC) 'community of innovators'. It aims to provide researchers testing innovations in mental health with a set of tools to help them develop their policy influence or engagement strategy towards desired/expected changes. The toolkit is designed to be used by project teams during planning days, team strategy workshops or in day to day planning activities. The Toolkit includes four main tools: 1 − AIIM – Alignment, Interest and Influence Matrix; 2 − Creating a policy influence plan; 3 − Being a knowledge broker; Identifying and accessing 'champions'. In particular, the tool 3 is useful for knowledge management and communication for a plan.

Part of interest: The entire document.

Target groups: Policymakers, CSOs, RPOs, Innovation business, intermediaries

→ **Link to the document**

27. LIVERUR Living Lab research concept in rural areas

The LIVERUR project's short-term objective is to improve knowledge of business models that grow in rural areas, including the understanding of their potential using living labs. LIVERUR created a platform RAIN for improving innovation business model in rural areas. The deliverable (D5.1) titled "Circular rural business hub: database for piloting and stakeholder involvement" contains some useful suggestions on stakeholder mapping. One of the resources of the platform is the LIVERUR toolbox on the use of living labs in rural areas. This toolbox is inspired by the Harmonisation Cube model. One of the faces of the cube is users' involvement. The toolbox describes the aspects to consider, the task to be accomplished in stakeholder involvement, and provide some specific tools to be used.

Part of interest: Both documents: the annexes of deliverable D5.1 and the part on user involvement, Pp.31-54 of the toolbox.

Target groups: Policymakers, Providers, CSOs, Innovation business, RPOs, Payers, Intermediaries

→ **Link to the document**

A.3 Partnerships and territorial coalitions

In defining the scene for RRI demand-driven innovation pilot in health one important element to be taken into account is the presence of structure and action of partnerships, networks and/or coalitions of actors active on common issues, such as healthcare, community wellbeing, local development, environmental sustainability, etc.

Facing up to complex challenges and needs, in fact, requires the involvement and engagement of different actors, with different experiences and knowledge. Partnerships (public-private ones but also multi-stakeholder partnerships) and networks represent an institutional way for different organisations to work together for a common objective, while maintaining one's own autonomy. Territorial coalitions are collective bodies (formal or informal ones) that share a common vision of the situation at hand, of the problems and challenges to be confronted, of the objectives to be pursued, and of the strategies and actions to reach them. This shared vision produces a common will to change the status quo by overcoming pre-established interests and the possible contrasts between the diverse actors involved. On the basis of the choice to operate through partnerships, networks or coalitions there is the awareness that acting individually each actor would not be able to manage complex societal challenges or to reach important social, economic and environmental goals. Therefore, territorial coalitions and partnerships might play a central role in promoting change or in facing up to complex challenges and needs of an ecosystem or a territory.

The resources collected under this subcategory provide information on practices and experiences based on partnerships and territorial coalitions and on how to promote their constitution and their management. Some of the resources are focused on the issue of effectively involving citizens and patient organisations in the partnerships.

In CHERRIES project, the establishment of territorial coalitions and partnerships for responsible innovation in health is a goal to achieve within the three regions involved in the project. In fact, different coalitions are or will be activated for: carrying out the pilots in the three territories; work on co-constructing the solution of the identified need; activating a change process towards a more open and inclusive healthcare innovation system. One of the main aims of CHERRIES, indeed, is to design a responsible and demand-oriented territorial policy mix, on the basis of the three RRI demand-driven innovation pilots, to embed them in the territorial policies and strategies while giving the territorial stakeholder groups an active role in shaping their environment.

What follows are the resources of this subcategory.

28. The MSP tool guide

The tool guide has been set up by Wageningen University & Research for promoting and supporting the establishment of Multi-Stakeholders Partnerships (MSP). The tool contains 60 methods for stakeholder partnerships, grouped by six purposes – connection, issue exploration, and shared language, divergence, co-creation, convergence, and commitment. The guide has been written for those directly involved in MSPs – as a stakeholder, leader, action researcher, facilitator, or funder – to provide both the conceptual foundations and practical tools that underpin successful partnerships.

Part of interest: The entire document.

Target groups: RPOs, Policymakers, Innovation Business, Professionals, Providers, Patients, CSOs

→ Link to the document

29. Maximising value from a United Kingdom Biomedical Research Centre: study protocol

This article (by Greenhalgh et al., 2017) presents an organisational study on the Biomedical Research Centres (BRCs) model of partnerships (using various approaches). BRCs are partnerships between healthcare organisations and universities in England. 'Partnerships for Health, Wealth and Innovation' has been established with multiple sub-themes (drug development, device development, business support and commercialisation, research methodology and statistics, health economics, bioethics, patient and public involvement and engagement, knowledge translation, and education and training) to support individual BRC research themes and generate cross-theme learning. The 'Partnerships' theme will support the BRC's goals by facilitating six types of partnerships through a range of engagement platforms and activities.

Part of interest: The entire article.

Target groups: Policymakers, RPOs, Innovation business, Patients, Providers, Payers, CSOs

→ Link to the document

30. The Quadruple Helix-based innovation model of reference sites for active and healthy ageing in Europe: The ageing@Coimbra Case study

The article (by Malva et al., 2018) describes the Ageing@Coimbra community case as a reference site of the European Innovation Partnership on Active Health Ageing based on the involvement of quadruple helix and its impact in Portugal. Ageing@Coimbra partners support a regional network of 70 stakeholders that build a holistic ecosystem in health and social care, taking into consideration the specificities of the territories, living environments, and cultural resources. Good practices in reducing the burden of brain diseases that affect cognition and memory impairment in older people and tackling social isolation in urban and rural areas are among the top priorities of Ageing@Coimbra. Profiting from the collaborative work of academia, business companies, civil society, and authorities,

the quadruple helix of Ageing@Coimbra support: early diagnosis of frailty and disease; care and cure; and active, assisted, and independent living. This experience is based on an innovative formula of development of federation of stakeholders and network inspired by the quadruple helix concept.

Part of interest: The entire document.

Target groups: RPOs, Policymakers, Innovation Business, Professionals, Providers, Patients, CSOs, Payers

→ **Link to the document**

31. Using the Quadruple Helix Approach to accelerate the transfer of Research and Innovation Results to Regional Growth

This Report (by Cavallini, Committee of the Regions, 2016) investigates the theory and the operationalisation of the so-called 'helices models' were the main protagonists of innovation-generating processes (industry, university, government, and, at a later stage, civil society) interact for accelerating the transfer of research and innovation results to regional growth. The analysis is principally carried out from the perspective of local and regional authorities (LRAs) and in the light of the potential impacts that the operationalisation at the regional level of such models may have on growth, in particular as reference for the development of Research and Innovation Strategies for Smart Specialisation (RIS3). The Report describes the practices and experiences of application.

Part of interest: The entire document and in particular the case GP7 case (Pp. 98-100).

Target groups: Policymakers, RPOs, Business Innovation, Patients and CSOs

→ **Link to the document**

32. Quadruple helix as a network of relationships: creating value within a Swedish regional innovation system

This paper (by Hasche, Höglund, and Gabriel Linton, 2019) describes and analyses a specific regional smart specialisation initiative taking place in Örebro (Sweden) on robotics that is investigated from a quadruple helix framework (industry, government, academia, and users/civil society). The aim is to understand the relationships and the value created between the different actors. From the results, the authors conclude that the fourth helix should be viewed as a whole – an arena where triple helix actors in different value-adding relationships take on different roles – where they create value to civil society, for example, new jobs or products for improved elderly care. Users in the quadruple helix framework can also be defined in several ways depending on the context of the arena (the fourth helix) and what value-adding activities they bring to civil society. Thus, users can be businesses, organisations, citizens, society, and many more things.

Part of interest: The second part of the article applies the quadruple helix framework to "Robotdalen" case.

Target groups: Policymakers, Payers, RPOs, Innovative Business, Providers, Patients, and CSOs

→ **Link to the document**

33. Riconfigure – Progress report for comparative analysis

This is the Progress Report on quadruple helix social labs carried out in the framework of Riconfigure project (Deliverable D6.5, 2020). It presents important questions such as the theory and the practices of quadruple helix collaboration; the integration of quadruple helix and RRI. The Report describes also barriers and obstacles to quadruple helix collaboration, such as s funding, role distribution, incentives, power structures, and path dependency. The general considerations arisen in the report are relevant also for social labs implemented in the healthcare sector.

Part of interest: The entire document.

Target groups: Policymakers, Providers, Professionals, Patients, CSOs, RPOs, Innovation business

→ **Link to the document**

34. Patient first: how Karolinska University Hospital is transforming to meet future demands of healthcare

The resource (2019) describes the partnership between Karolinska Hospital and Philipps in providing imagining devices and in reorganising the hospital care services. The new organisation for the Hospital of Solna is organized in patient care flows. For example, patients with heart and vascular conditions are treated in an integrated manner, with specialists from functions such as emergency medicine, imaging, and cardiology working together – often in the same building or corridor. In this framework, Karolinska and Philips agreed on a managed equipment services model: Philips coordinated the procurement and commissioning of all required imaging equipments; took on responsibility for the coordination of transport, installation, and commissioning of equipment, and for the training of staff.

Part of interest: The entire document,

Target groups: Providers, Professionals, Innovation Business

→ **Link to the document**

35. Inventory of bottom-up governance innovation practices

This document (TeRRItoria Project, Deliverable D3.1, 2019) contains an Inventory of 30 bottom-up governance innovation practices. The Inventory focuses on those governance innovations, promoted by different kinds of coalitions, that activate a process of "re-territorialisation", i.e., they work for reversing de-territorialisation trends and thus to foster local development and social cohesion. In particular, the Inventory collects the experiences in which research and innovation actors, in different ways, exercise responsibility toward their territory as they play a pivotal role in governance innovation. The territorial coalitions promoted and implemented practices aimed at: re-rooting economic and social activities; recovering and fostering local knowledge; establishing new regulatory frameworks; preventing and managing environmental, social, and economic risks; setting the agenda for defining strategies and actions to solve local problems. The introduction describes the

methodology used to set up the Inventory. Some of the practices identified are dealing with healthcare and in particular the practice #11 − Permanent living lab for the governance of city issues including health; #30 − Use of dialogue model for health research agenda-setting process; as well as #31 (but not related to partnership *strictu sensu*) humanizing healthcare in hospital by art and technology.

Part of interest: The entire document and in particular the Inventory, Pp.14-107.

Target groups: Policymakers, Providers, Professional, Patients, CSOs, RPOs, Innovative business, intermediaries

→ **Link to the document**

36. VINNOVA – Challenge Driven Innovation

Challenge Driven Innovation (CDI) is a research and innovation-funding programme developed by the Vinnova's Swedish Innovation Agency to fund collaboration in research and innovation that address societal challenges (including future healthcare) addressing Agenda 2030 goals, involving consortia of partners from different parts of society. The program foresees the inclusion of different actors in the project; supports a problem-oriented and demand-driven approach that necessitates anticipation and reflection; encourages learning by doing and responsiveness and capacity of changing and adapting. Gender equality is an important element of CDI. Participation in the CDI program requires the constitution of consortia, involving different kinds of stakeholders during the entire duration of the project, for co-creating and implementing a solution to an identified need/challenge.

Part of interest: The entire document.

Target groups: Payers, RPOs, Innovation Business, Policymakers

→ **Link to the document**

37. Sparks Handbook for participatory activities

SPARKS is an awareness-raising and engagement project to promote RRI across 29 European countries (EU members plus Switzerland and the UK) and science engagement activities on RRI in health and medicine. This resource is focused on participatory activities for organizing exhibitions and events, and it is articulated in the following parts: rethinking innovation together; innovative participatory activities on RRI (science cafés, pop-up Science Shops, incubation activities and scenario workshops); capturing the scene; guidelines to plan of the work, establishment of local partnerships; different kind of activities, templates for the organizers. The resource contains also experiences and practices. The Handbook provide also advice on how organise and manage a local partnership for the design and the development of an exhibition assigning to the local partners a role as RRI ambassadors.

Part of interest: See the part on the establishment of a local partnership.

Target groups: Policymakers, RPOs, Patients and CSOs, Innovation business, Science centres and Museums

→ **Link to the document**

38. Rapid Policy Network Mapping

The article (by Bainbridge, Potts, O'Higgins, 2011) offers a method for policy network analysis referred to as "Rapid Policy Network Mapping", which gives insights into relationships and dependencies of policy development in the environmental domain. The resource describes the application of its method to the definition of the Marine Strategy Framework Directive and the Water Framework Directive in the UK, in which local policymakers and civil society organisations and citizens worked together. This tool should assist civil society in its ability to understand and influence policymaking and implementation. The proposed method facilitates the understanding in a network the relations among policy actors and policy instruments.

Part of interest: The entire article.

Target groups: Policymakers, RPOs

→ **Link to the document**

39. Ängen research and innovation

Ängen is a collaboration with researchers, innovators, caregivers, elderly, and people with disabilities and constitutes a platform where developers and users can meet. Ängen is running several development projects. The purpose is to develop new technical solutions/assistive devices that allow the elderly and disabled to stay longer in the home environment while maintaining independence and integrity. Ängen is a so-called PPP (Private/Public Partnership) and is funded by Örebro University, Örebro municipality, Alfred Nobel Science Park, Länsgården real estates AB and EU.

Part of interest: The entire document.

Target groups: Providers, Innovation business, RPOs

→ **Link to the document**

40. UDI – Civilsamhälle och närsjukvård – nya samverkansformer och överenskommelser (Civil society and local healthcare – new forms of collaborations and agreement)

The report describes a collaborative project between Karlskoga Municipality, the healthcare in the western healthcare district of Örebro county, and Möckelnföreningarna, an umbrella organisation for civil society organisations. The project has aimed to find new ways to collaborate and to find new solutions for societal issues through extended cooperation. The project was funded by Vinnova (Sweden's innovation agency) within the Challenge-Driven Innovation calls: in particular, it received the fund for the Stage 1 initiation and is being funded also for Stage 2.

Part of interest: The entire document.

Target groups: Providers, Innovation business, RPOs

→ **Link to the document**

A.4. Starting the process

As stated before, CHERRIES project aims to promote a process of change in the way of doing innovation in healthcare in order to be able to better respond also to unmet needs of society and to align science to society, by embedding RRI keys (ethics, science education, gender equality, public engagement, open access, and governance) and dimensions (anticipation, inclusion, reflexivity, responsiveness). In other words, the aim is to promote a more open, innovative, and inclusive healthcare ecosystem in the three territories involved in the pilots. This will require to start a process of institutional change in the procedures, practices, rules, and values. In order to achieve a systemic change, the process should involve key organisations of the territorial healthcare and innovation ecosystem.

Institutional change is related not only to modify rules and procedures, or to set up new institutional frameworks or a platform for multi-stakeholder dialogue and citizen engagement. Institutional change requires also to transform the behaviour and culture of the involved actors. Such changes require time, learning initiatives, incentives, and support. Furthermore, the process of change might meet obstacles and resistances as well as enabling factors and opportunities.

The resources collected in this sub-category provide suggestions and indications for interpreting the complex process of institutional change and for answering the fundamental questions on how to start this process. They address issues such as, among others: understanding the situation and identifying the objective of the change; create a team capable of leading the change process; carry out design and planning activities; guaranteeing multi-stakeholder dialogue and citizen engagement; involve the organisation's leadership in supporting the process. The resources have been produced mainly in the context of those EU projects that during the last ten years have tested several approaches and methods to start and implement institutional change processes in research organisations, funding and intermediary organisations, higher education institutions, in industry and SMEs companies. Some additional resources document also a more recent trend in European projects, aimed to apply RRI approach to territorial governance.

The following are the resources on starting and implementing the institutional change process.

41. Starting the process. Guidelines on governance settings for responsible and open science

The document (Fit4RRI Project, Deliverable D5.1, 2019) contains Guidelines for interpretation, decision, and action aimed at implementing RRI in research organisations, with particular attention to governance settings aspects. It provides recommendations about the triggering factors for institutionalising RRI, enabling factors and obstacles, stakeholders to be involved, etc. The Guidelines contain also links and references to resources to be used for implementing RRI.

Part of interest: The entire document.

Target groups: RPOs

→ **Link to the document**

42. Guideline on RRI implementation in Bioscience organisations

The document (STARBIOS2 Project, Deliverable D9.1, 2019) contains a model and Guidelines for promoting structural change to attain RRI in bioscience research organisations. The model has been set up on the basis of the implementation of Action Plans for RRI structural change within 9 biosciences organisations in the following countries: Italy, Poland, UK, Slovenia, Germany, Bulgaria, USA, Brazil, and South Africa.

Part of interest: See in particular part 4 "The structural change process in practice".

Target groups: RPOs, Innovation Business, Higher Education Institution

→ **Link to the document**

43. Towards a Sustainable and Open Science. Recommendations for Enhancing Responsible Research and Innovation in the Biosciences at the University of Bremen

The document (by Elster, Barendziak, Birkholz, 2019) provides, on the basis of the implementation of an Action Plan with the University of Bremen carried out in the framework of STARBIOS2 Project, recommendations and suggestions in the RRI field of education. Each recommendation contains links to resources and documents.

Part of interest: The entire document.

Target groups: RPO, Innovation Business

→ **Link to the document**

44. Maps of Approaches, Policies and Tools for Territorial RRI

The Map (TeRRItoria Project, Deliverable D3.3, 2019) highlights what are the core issues related to a territorial RRI: the transformations in society; the "de-territorialisation" process; the "territory-making" practices aiming at dealing with de-territorialisation and activating a re-territorialisation (i.e., the development of new meaningful relations among actors and between them and their territory); the territorial dynamics in European landscape; etc. The Map is based on two inventories: on RRI governance innovation practices and on bottom-up governance innovation practices. On the basis of the practices collected, the first list of approaches to Territorial RRI has been set-up. Some practical reference tools (guides, toolkits, regulations, books, articles, etc.) for embedding Territorial RRI are also presented, together with many examples of practices.

Part of interest: See in particular chapters #3, #4, and #5 on Territorial RRI; chapter #6 on tools.

Target groups: Policymakers, Providers, Professional, Patients and civil society, RPOs, Innovative business, intermediaries, Funding organisations, payers

→ **Link to the document**

45. Towards regional responsible research and innovation? Integrating RRI and RIS3 in European Innovation Policy

This article (by Fitjar, Benneworth, Asheim, 2019) develops a model for a regional RRI policy, integrating existing European Union policies on RRI in Smart Specialisation Strategy (RIS3). In particular, it contains the inclusion of the geographical element in RRI and a responsible approach of RIS3 based in general on a more inclusive stakeholder engagement and the application of four dimensions of RRI: anticipation, inclusion, reflexiveness, responsiveness. In particular, the approach foresees the inclusion in the RIS3 phases of analysis, governance, vision, prioritisation, policy mix, and monitoring the four dimensions of RRI.

Part of interest: The entire article.

Target groups: Policymakers, RPOs, Innovation Business, Intermediaries, Higher Education Institutions, CSOs

→ **Link to the document**

46. Nucleus implementation Road Map

The NUCLEUS project focuses on identification of key factors for successfully embedding RRI in academic practices. The Implementation Roadmap (Deliverable D3.6, 2017) introduces steps and actions to install 10 embedded Nuclei and 20 mobile Nuclei as innovative and reflective RRI test-beds. It provides also recommendations based on NUCLEUS first phase of activities. This resource might be useful in general for embedding RRI in organisations and contextualisation, but also for building the community/partnership that will be involved.

Part of interest: See, Summary (Pp. 5-6), and Part 1 building the community (Pp. 10-11).

Target groups: Policymakers, Patients and CSO, RPOs, Innovation Business, Higher Education Institutions, Intermediaries, Providers

→ **Link to the document**

47. Materials for fostering up-take of Co-RRI

This document (FoTRRIS Project, Deliverable D4.4, 2018) collects all the tools FoTRRIS produced that are necessary to inspire and to guide an interested quadruple helix actor to set up a co-RRI competence cell or to orchestrate a co-RRI transition experiment. In particular, the following tools produced by FoTRRIS are interesting: how to set up a competence cell; how to use the FoTRRIS online platform; Cookbook is included: how to co-create RRI projects.

Part of interest: See in particular "Cookbook: how to co-create RRI projects.

Target groups: Policymakers, RPOs, Business, CSOs, Higher Education Institute

→ **Link to the document**

48. Policy Recommendations for Co-RRI

This document (drafted in the framework of FoTRRIS project Deliverable D4.3, 2018) contains, in the first part, a definition of co-RRI (co-created Responsible Research and Innovation) and, in the second part, recommendations for implementing Co-RRI at the level of the country system. The co-RRI is an adaptation of RRI at the territorial and glocal challenges.

Part of interest: See the first part devoted to the presentation of co-RRI.

Target groups: RPOs, Innovation business, intermediaries, Higher education institutions

→ **Link to the document**

49. Implementing Responsible Research and Innovation in ICT for ageing society

This is the Executive Brief of Responsible Industry project (by Porcari et al., 2015). Responsible Industry aims to integrate principles and methodologies of RRI into the research and innovation processes developed by industries active in the domain of ICT for an ageing society. The resource contains a Framework for the Implementation of RRI providing strategic options and recommendations for industrial actors engaged in R&I to enable them to pursue responsible practices and behaviours in developing devices, products, and services.

Part of interest: See in particular Part 2 on the RRI framework to be implemented in R&I industry.

Target groups: RPOs, Innovation business, CSOs, Providers

→ **Link to the document**

50. Responsible Innovation Co-Creation Method Kit

This kit set up in the framework of COMPASS project (Deliverable D2.5) is for the use of Business Support Organisations or others keen to support companies in designing Roadmaps towards Responsible Innovation (RI) in the areas of nanotechnology and/or healthcare innovation. The toolkit presents in a clear and easily readable form how to set up phone calls which last about 20 minutes with company leaders and how to introduce them to RI and how to get them involved and how to use findings from these interviews to build custom web forums and webinars. The methods presented are tailored towards SMEs, for example by emphasizing the benefit of the inclusion of RI principles into daily SME practices. SMEs are taught foresight techniques and are aided in constructing a road map.

Part of interest: In particular, from Pg. 6 to Pg. 43.

Target groups: RPOs, Innovation Business, Start-ups

→ **Link to the document**

51. PRISMA RRI Exemplar Road Map

This document (2019) provides guidelines to develop long-term strategies (roadmaps) to innovate responsibly, integrating technical, ethical, social, environmental, and economic issues into research and innovation practices, by improving the ethical and social impacts of their outcomes. The focus is on transformative and enabling technologies. The road mapping includes 6 steps: commitment and leadership; context analysis; materiality, experiment, and engagement; validation; road map design. The road map uses the 4 dimensions of RRI; the key elements are: product research and innovation; vision of RRI in implementing the product; time scale; drivers, challenges and barriers; actions to be pursued, resources, and process needed.

Part of interest: See in particular Section 6.6. "Validation".

Target groups: Innovation business

→ **Link to the document**

52. Act on Gender Community of practices co-creation toolkit

The document was drafted in the context of the ACT for gender equality project Community of practices (CoP). The toolkit describes 20 different participatory methods, online methods, and visual methods. It shows how and which tools and methods the CoPs might operate, develop, implement gender equality plans (GEP), gender equality (GE) measures and activities, and facilitate institutional change concerning GE in HE and R&I. Such methods might be useful in implementing the 6 steps for the process of setting up, implementing, monitoring and evaluating GEPs. It contains also information about success factors, life cycle, and activities of a COPs that requiring the participation and involvement of different actors.

Part of interest: The entire document, and in particular chapters #7, #8, and #9.

Target groups: RPOs, Higher Education Institutions, CSOs, Payers, Innovation Business

→ **Link to the document**

53. GRACE – Grounding RRI Actions to Achieve Institutional Changes in European Research Funding and Performing Organisations – Resources

GRACE's mission is to develop a set of specific Grounding Actions in six performing and funding organisations (Implementing Organisations). These actions are the basis for the development of a tailored 8-year RRI Roadmap within these organisations to ensure its sustainability and full implementation over the long-term. On its page "Resources" there are resources developed by GRACE and other initiatives related to implementing Grounding RRI Actions to Achieve Institutional Changes. Among others, it presents six guidance on the six keys of RRI, a state of the art review of documented experiences as a basic scheme for self-assessment, a questionnaire about the use of the guidance, and a reflection tool for starting RRI initiative.

Part of interest: The six guidance and the reflection tool.

Target groups: RPOs, Higher Education Institutes, Innovation Business, Payers

→ **Link to the document**

54. PRAGES Guidelines for Gender Equality Programmes in Science

The document (PRAGES Project, 2009) contains the outcome of the project, whose main objective has been to take stock of programmes and initiatives found in specific institutional settings (such as universities, institutes, faculties, and departments, but also networks, associations, and S&T-related enterprises) aimed at promoting gender equality in S&T. The Guidelines are composed by 5 parts: part A Women and science: problems at issues at stake; part B Strategy one: a friendly environment; part C Strategy two: gender-aware science; part D, Strategy three – women's leadership of science in a changing society; part E Programmes that work.

Part of interest: See in particular, the summary charts, Part E "Programmes that work".

Target groups: RPOs, Higher Education Institute

→ **Link to the document**

55. Structural Transformation to Achieve Gender Equality in Science – Guidelines

The document (Stages Project, Deliverable D8.3, 2015) contains a description of action plans for promoting institutional change towards equal opportunity in science and provide useful recommendations for implementing structural change action plans.

Part of interest: The entire document. In particular recommendations I "Collecting data and monitoring gender equality" and II "Engaging leadership".

Target groups: RPOs, Innovation Business, Higher Education Institution

→ **Link to the document**

56. Triggering institutional change towards gender equality in science

The Guidelines (Trigger Project, Deliverable D7.5, 2017) provides orientations and analyses to manage what may happen when, in a given research organisation, a gender action plan is launched (be it promoted by a specific project team, the HR Department, the Rector, the Head of a department or other internal stakeholders). The Guidelines take into account also a wider debate on institutional change towards gender equality involving representatives of other 8 EC-funded structural change projects.

Part of interest: The entire document. In particular part 1 "Transformational agent".

Target groups: RPOs, Higher Education Institute

→ **Link to the document**

57. Technological Responsibility. Guidelines for a shared governance of the process of socialisation of scientific research and innovation, within an interconnected world

The Guidelines (SET-DEV Project, 2011) are the result of dialogue and cooperation between representatives of three major scientific cultures of Europe, India, and Africa. The Guidelines are a practical contribution about how can be promoted effective collective responsibility in science and technology and how scientific and technological research can better integrate into society and be more relevant to society's needs. In particular, the document is centred on the concept of socialisation of scientific and technological research and its areas (scientific practice; scientific mediation, scientific communication; evaluation; innovation; governance; gender; substantive approaches). For each of these areas, several frames of responsibility are outlined which act as reference points for identifying problems and finding solutions concerning the relationship between science technology, and society.

Part of interest: In particular, see the general summary with the list of frames of each area, at Pp.21-35.

Target groups: Policy Makers, RPOs, Innovation Business, Intermediaries, Higher Education Institutions

→ **Link to the document**

B. Making the process of needs identification in health more open, inclusive and responsive to territorial/societal challenges

RRI experiments in the health sector in CHERRIES are based on demand-driven and open innovation approaches that address the emerging needs of the sector. Open innovation in Health means to build more "porous" innovation systems, establishing innovative forms of collaboration among different kinds of actors. In this framework, needs, evidence, and data are generated openly and collaboratively; ideas can come from anywhere; innovation is informed also by the needs of patients and the knowledge of practitioners.

In this respect, a cornerstone of the CHERRIES methodology is the adoption of a participatory and inclusive approach in the identification and articulation of health needs as foundation of demand-driven care and innovation policies. This is important in order to better align the directionality of the research and innovation process with the territorial and social health challenges, implementing what could be called a "responsibility-by-design" approach in identifying research priorities and the demand for innovation.

Application of the RRI framework can help regional health ecosystems to become more open, inclusive, and responsive to unmet health needs through broader involvement of societal actors and citizens and the "incorporation" of different societal perspectives and different kind of "knowledge" and expertise (e.g., "experiential" knowledge of patients and citizens about healthcare systems problems or specific diseases). Their involvement in the decision-making process might allow a more socially aligned identification of needs and priorities in health at territorial level.

In this section of the Toolbox, a selection of some innovative experiences related to EU projects or territorial partnerships/coalitions for R&I in health is provided. Indeed, in such projects, a concrete application of a RRI and demand-driven approach for the understanding and the inclusion of unmet needs in health was experimented and assessed as valuable. In this framework are presented, for instance, participatory practices of involvement of citizens and relevant healthcare stakeholders, examples of the adoption of the patient-centric approach in health innovation, or the inclusion of citizen concerns and needs through the implementation of Citizen science or Community-Based Participatory Research Approach in health. Finally, some examples and tools concerning the arrangement of "Calls" aimed at the identification and selection of relevant needs for innovation are provided.

To this end, the resources of this second section are arranged within the following 3 sub-categories:

B.1. Demand-driven and user-led/people-centric/open innovation approaches in healthcare

B.2. Participatory approaches and methods for patient and stakeholder engagement for research agenda setting in health

B.3. Calls for needs, Calls for challenges, Open Innovation Calls in health

B.1. Demand-driven and user-led/people-centric/open innovation approaches in healthcare

People-centred health systems and Patient-User-Citizen centred approach are a new emerging paradigm in health, oriented to improve the quality of the health research results and to devise more effective clinical trials. These approaches are also very important for a better alignment of the innovation lifecycle with societal needs, concerns, and preferences.

Patient-centredness is an approach to healthcare that consciously works around patients' needs, responding to individual preferences, and trying to ensure that patient values guide clinical decisions. Patient-centricity in health care is therefore of an enormous importance. It is a way in which health care systems can establish a partnership among practitioners, patients, and their families to align decisions with patients' wants, needs, and preferences.

Here below are presented several resources concerning the adoption of this approach in health. They are both articles and papers containing theoretical and methodological elements on these approaches and, or technical tools and examples including instruction on issues as engagement of patients and citizens; public-private partnership creation; patients' needs identification. Examples come mainly from European experiences and in particular from Innovative Medicines Initiative − IMI projects (like for instance Paradigm of PREFER Project), or other relevant practices identified from other sources. Also examples of Policy program based on patient-centric approach (e.g., in ageing) are provided.

What follow are the resources of this subcategory.

58. The role of need in open and user-led innovation approaches in healthcare

This webinar is part of the first series of episodes promoted by CHERRIES, aimed at exploring relevant aspects for the approach of the project and of the territorial RRI experiments in order to shape more open, inclusive, and sustainable regional healthcare ecosystems. In this webinar, the focus was put on the demand-driven and the role of patient/led user innovation in health. A focus was posed on the role of user/patient and need-based innovation in healthcare, user-producer interactions, regulation, and knowledge production in emerging technology fields. Several questions, and answers, were revolving around the need identification between actors with different perspectives and the implementation of innovation cultures in and between organisations.

Part of interest: The entire webinar.

Target groups: Policymakers (local authorities), Providers, Professional, Patients, CSOs, RPOs, Innovative business, intermediaries

→ **Link to the document**

59. Success factors of Demand-driven Open Innovation as a Policy Instrument in the Case of the Healthcare Industry

In this article (by Pikkarainen, Hyrkäs, Martin, 2020) are presented the results of a longitudinal study on the success factors of the experience of demand-driven open innovation in health experimented within the framework of the InDemand Project. The focus of the paper is to explore a digital health open innovation ecosystem over the years. The results show that the created demand-driven open innovation model can be used to strengthen the governance of digital health and to improve communication density and knowledge transfer between the ecosystem actors. The findings help policy-makers to use open innovation as a policy instrument supporting hospital and company managers to increase understanding of the opportunities of demand-driven open innovation.

Part of interest: The entire paper.

Target groups: RPOs, Innovation business, Policymakers, Patients, Providers, Professionals

→ **Link to the document**

60. IMI Innovative medicine initiative

The Innovative Medicines Initiative (IMI), is a Public-Private Partnership initiative (PPP) between the European Union (represented by European Commission) and the European pharmaceutical industry (represented by EFPIA) aimed at improving health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social needs and by facilitating collaboration between the key players involved in health research. By bringing these diverse groups together around one table, the IMI projects can accelerate the development of innovative solutions to the most pressing medical burdens of our time, including antimicrobial

resistance, dementia, diabetes, and cancer. The IMI calls for proposals require the participation of citizen and patient organisations that are invited to become a partner in a project by proposing ideas and suggestions.

Part of interest: See the section "The IMI call process" and its annexes.

Target groups: RPOs, Innovation business, Policymakers, CSOs, Patients, Payers, Providers, Professionals, Intermediaries

→ **Link to the document**

61. PARADIGM "Patient Engagement Toolbox"

The Project "PARADIGM" (Patients Active in Research and Dialogues for an Improved Generation of Medicines), a public-private partnership co-led by the European Patients' Forum and EFPIA, aimed at providing a unique framework that enables structured, effective, meaningful, ethical, innovative, and sustainable patient engagement (PE) along the lifecycle of medicines and demonstrates the 'return on the engagement' for all players. In the project framework, the PARADIGM Toolbox was developed. It is a comprehensive set of tools and practices to support the integration of the patient perspectives into medicine development beyond the focal areas of the project. In the Toolbox are included the PARADIGM co-created recommendations, tools, and relevant background information to make patient engagement in medicines development easier for all.

Part of Interest: See in particular, sections on "Planning patient engagement" and on "Conducting patient engagement".

Target: Patients and relevant stakeholders in Healthcare

→ **Link to the document**

62. An overview of critical decision-points in the medical product lifecycle: where to include patient preference information in the decision-making process?

PREFER Project is aimed at strengthening patient-decision making throughout the life cycle of medicinal treatments by developing expert and evidence-based recommendations on how patient preferences should be assessed and inform decision making. In this PREFER's article (Whichello et al., 2020) a roadmap for including patient preference in the life cycle of medical treatment is proposed. Recommendations to support the development of guidelines for industry, Regulatory Authorities, and HTA bodies, based on a patient-centric approach are included.

Part of interest: The entire article.

Target groups: RPOs, Innovation Business, Patients, Professionals, Providers

→ **Link to the document**

63. NESTORE – Your pathway to wellbeing

NESTORE is an innovative personalised ICT coaching system to support healthy ageing, based on co-design principles. The NESTORE system aims at putting the user at the core of the design process in order to address one of the biggest challenges of our century: "how to develop technologies that are useful and usable for the target users?". The need collection of users, made by involving 80 older people communities in the UK, is described in the deliverable D7.1. "Needs, values, and suggestions to Co-design"; the further co-design for improving the prototype is described in deliverable D7.3 "Report on end-user improvement for prototypes", related to the validation initiatives with stakeholders carried out in 3 EU countries.

Part of interest: See Deliverables D7.1 and D7.3.

Target groups: Policymakers, Providers, RPOs, Business Innovation, High Education Institutions

→ **Link to the document**

64. Social Impact Lab – innovation to overcome societal challenges

This is a practice promoted by Örebro University. Social Impact Lab (SoIL) is an innovation environment and a programme that focuses on innovations for social sustainability. The programme provides support and expertise for innovative idea development over twelve months, with regular meetings one day a week, involving citizens and stakeholders. At SoIL, researchers and teaching staff from Örebro University participate, as well as staff from other organisations, in creating the right conditions for collaboration and innovation.

Part of interest: The website page.

Target groups: RPOs, CSOs, Innovation business, Policymakers, Payers

→ **Link to the document**

65. Innovation home care – Generating new solutions through addressing unmet needs identified by formal and informal healthcare providers

This is a Joint thematic policy transfer report made in the framework of Interreg project HOCARE. It is focused on how to boost innovation in-home care by generating new solutions addressing unmet needs identified by formal and informal healthcare providers. It contains a summary of common problems and challenges in generating innovations in-home care based on addressing the unmet needs of healthcare providers and on the identification and analysis of selected good practices in this field. It provides also a transferability matrix and analysis of the identified best practices.

Part of interest: See in particular from Pg. 5 to 9 and from Pg. 27 to 42.

Target groups: Policymakers, Providers, professionals, Innovation Business, Patients

→ **Link to the document**

66. GET Project – Methods to identify unmet needs in eHealth

This document (GET Project "Delivering Growth to Health Business" − 2015) aims to support entrepreneurs and Small and Medium Enterprises (SMEs) to identify unmet needs in eHealth following a demand-driven approach, through the provision of methods for implementing in concrete this new perspective.

Part of interest: The whole document.

Target groups: Entrepreneurs and SMEs in e-health

→ **Link to the document**

67. Policy brief 22. How to strengthen patient-centredness in caring for people with multimorbidity in Europe?

The Innovating care for people with multiple chronic conditions in Europe (ICARE4EU) project was focused on improving care for people with multiple chronic conditions (multimorbidity) in European countries. An estimated 50 million people in Europe live with multimorbidity. The complex health problems of these people and their needs for continuous and multidisciplinary care pose a great challenge to health systems and social services. This Policy brief #22 of Icare4Eu project provides insight into how patient-centred care is currently incorporated in innovative care programmes in Europe for people with multimorbidity. It is aimed at facilitating policy-makers in the development of policies directed at patient-centred care for people with multimorbidity.

Part of interest: The whole document.

Target groups: Policymakers, Providers, Professionals, Innovation Business, RPOs, Patients, CSOs

→ **Link to the document**

68. Ageing Better in the Netherlands

This article (by de Jong, Wynia, Geluk-Bleumink, 2018) presents an interesting example of the "Care for Elderly Program" in which a patient-centric approach is adopted. The Dutch National Care for the Elderly Programme was an initiative organized by the Netherlands Organisation for Health Research and Development (ZonMw) between 2008 and 2016. The programme aimed to collect knowledge about frail elderly, to assess their needs, and to provide person-centred and integrated care better suited to their needs. Putting the needs of elderly people at the heart of the programme and ensuring their active participation was a key to the programme's success.

Part of interest: The entire article.

Target groups: Policymakers, RPOs, Innovation Business, CSOs, Higher Education Institutions, Providers

→ **Link to the document**

69. Inventory of bottom-up governance innovation practices

This document (TeRRItoria project, Deliverable D3.1 − 2019) contains an Inventory of 30 bottom-up governance innovation practices. This Inventory is part of a broader work aiming at identifying useful examples, in terms of approaches, policies, and tools, for the development of the 5 "Transformative Experiments" of territorial RRI the project is going to implement. The Inventory focuses on those governance innovations, promoted by different kind of coalitions, that activate a process of "re-territorialisation", i.e., they work for reversing de-territorialisation trends and thus to foster local development and social cohesion. In particular, the Inventory collects the experiences in which research and innovation actors, in different ways, exercise responsibility toward their territory as they play a pivotal role in governance innovation. In particular, three of the practices of the inventory are focused on health, and it has been set up on the basis of citizen and people needs (including health) and active involvement. These practices are: #11 Living Lab to facilitate learning and collaboration; #22 Cooperation among public services around a local library; and #30 Application of the Dialogue Model for health research agenda-setting process.

Part of interest: The entire document. See in particular: Practice #11; Practice #22; Practice #30.

Target groups: Policymakers (local authorities), Providers, Professional, Patients, CSOs, RPOs, Innovative business, intermediaries

→ **Link to the document**

70. Public and patient involvement in needs assessment and social innovation: a people-centred approach to care and research for congenital disorders of glycosylation

The article (by De Freitas, Dos Reis, Silva, Videira, Morava, Jaeken, 2017) describes an experience of need identification of people with Congenital Disorders of Glycosylation (CDG) to elicit social innovations and to promote people-centred care and research. The needs were collected by the implementation of focus groups involving patients, parents and providers, and professionals. The article contains tables summarizing the needs identified during the experience.

Part of interest: The entire article.

Target groups: Patients, CSOs, Professionals, Providers

→ **Link to the document**

B.2. Participatory approaches and methods for patient and stakeholder engagement for research agenda setting in health

Under this sub-category are arranged some relevant resources more focused on the presentation of approaches and methods for setting up a participatory agenda in health with a bottom-up need identification process. Such approaches can be useful when designing a "Call for needs" (see point B.3.) and can also serve as a more general source of inspiration for a possible embedment of demand-driven/participatory approaches for R&I agenda setting in health within territorial healthcare ecosystems.

These resources concern approaches and tools for the design and implementation of a multi-stakeholder dialogue for priority setting in health research or the identification of territorial societal challenges or unmet needs in health. They were selected from the analysis of some relevant and successful experiences developed during the last years of participatory approaches and methods applied for multi-stakeholder dialogue and research agenda priority setting in health. Setting up a participatory research agenda has multiple advantages: apart from helping to identify stakeholders' unmet needs and what matters to end-users, it also helps researchers to include new perspectives in research, prepare stakeholders for the research process, structure the process for broader collaboration between stakeholder groups, and enable and empower stakeholders to make their voice heard.

Among these resources, there are examples of participatory methods and practices for the promotion of public consultation and dialogue activities within a given territory. As CHERRIES experience shows, these preliminary consultation activities are important for identifying social needs that can be integrated into research project aims or innovation demand definition or in funding calls or in Calls for solutions (see section C). To this end, the publishing and the spread of specific "Calls for needs" in health (see next subcategory) might be more effective and successful if accompanied, in parallel, by an articulated public consultation and dialogue itinerary with key relevant territorial actors and citizens of the region.

What follows are the resources concerning this subcategory.

71. Patient involvement in Lung Foundation Research (NLF): A seven years longitudinal case study

In this article (by Teunissen, Visse, Laan, 2013) are provided the results of 7 years of longitudinal analysis of the experience of patient involvement implemented by the Lung Foundation Netherland. NLF can be considered an inspiring practice of RRI institutional change in health for the adoption of a paradigm shift in the research process through patient involvement. NLF holds an extensive network including researchers, health professionals, and patients that are included in the agenda-setting activities. It developed various forms of patient involvement for promoting needs-oriented research: changing its guidelines for proposal writing, communication with patients; participation in projects.

Part of interest: The entire document.

Target groups: RPOs, Innovation business, Patients, CSOs, Payers

→ **Link to the document**

72. Mind the gap! Multi-stakeholder dialogue for priority setting in health research

This inspiration guide sets out different methods that can contribute towards the success of a multi-stakeholder dialogue for participatory priority setting in health research. A process of participatory and deliberated research priority setting involving all stakeholders can assist researchers and policymakers in effectively targeting research that has the greatest potential benefit to patients, the public, and society. The guide is based on a workshop organized by the King Baudouin Foundation with researchers, patients, patient organisations, care providers, pharmaceutical companies, and research funding bodies. In the document are illustrated the five steps of the Dialogue Model (exploration; consultation; prioritisation; integration; programming; implementation).

Part of interest: The whole document. See in particular the 3 examples of implementation; a reflection on the benefit for such participatory priority setting; the basic elements of this kind of activity

Target groups: Patients, CSOs, Policy Makers, Providers, Professionals, Innovation business, Payers

→ **Link to the document**

73. Patient participation as dialogue: setting research agendas

In this article (by Abma, Broerse, 2010) is presented a study aimed at developing a methodology for health research agenda-setting processes grounded in the notion of participation as dialogue. Seven cases were studied to develop and validate a Dialogue Model for patient participation in health research agenda-setting.

Part of interest: The whole article.

Target groups: Patients, CSOs, Policy Makers, Providers, Professionals, Innovation business

→ **Link to the document**

74. Cimulact Inspiration catalogue for consulting different groups

This catalogue, set up in the framework of Cimulact Project, contains a description of methods for involving different groups of stakeholders and citizens in participatory research agenda-setting, that can be applied in various fields including health. Among these methods, can be mentioned: citizens' vision workshop; vision clustering workshop; research agenda camp (co-creation workshop); who, what & why method; consensus workshop; enrich by co-design; prototyping research programme scenarios; the caravan; group interview with a co-design session; etc. The catalogue contains also a glossary, a table on the usefulness of citizen/stakeholder participation, and guidelines on recruitment. The resources of the catalogue can be usefully implemented also in healthcare.

Part of interest: See in particular Citizen's vision workshop and Vision clustering workshop.

Target groups: CSOs, Policymakers, RPOs, Innovation business, Payers, Providers

→ **Link to the document**

75. The James Lind Alliance Guidebook

The "James Lind Alliance (JLA) Guidebook" provides guidance about how to apply the JLA patient-involvement methodology for setting research priorities in health named "Priority Setting Partnership" (PSP). This JLA Guidebook contains methods, principles, and steps on how to establish a priority setting partnership and also useful examples of application. JLA has been working to identify research priorities in more than 40 areas including emergency medicine, palliative and end of life care, kidney transplantation, and autism. The JLA approach involves a combination of surveys and workshop interactions between patients, carers, and health care professionals to identify and agree on a "Top 10" list of research questions, aimed to highlight important areas for research.

Part of interest: The entire Guidebook.

Target groups: RPOs, Policymakers, Innovation Business, Professionals, Providers, Patients, CSOs

→ **Link to the document**

76. Engaging people with MIC (Mild Cognitive Impairment) in ageing and dementia research – The Abingdon Afternoon Tea Club

This resource describes an innovative practice of patient engagement in health research on dementia promoted by the NIHR Oxford Health Biomedical Research Centre (UK). The Centre set up an innovative solution for engaging people with MCI (Mild Cognitive Impairment) diagnosis in research, by organising the "Abingdon Afternoon Tea Club (AATC)", to connect people with MCI with the information they seek and to set up an informal network of people with experience of the condition.

Part of interest: the entire document.

Target groups: RPOs, Providers, Patients, CSOs, Professionals

→ **Link to the document**

77. The Irsi Caixa Living Lab for Health for multi-stakeholder engagement on health challenges

The Living Lab for Health at IrsiCaixa (Barcellona) aims to transform the Research and Innovation (R&I) system to make it more open, inclusive, and transdisciplinary inspired with methodologies that follow RRI and Open Science & Open Innovation criteria. This Lab promotes multi-stakeholder engagement interfaces where different actors are invited to participate in the R&I process at different phases of the value chain (priority setting, project design & execution, implementation, evaluation, dissemination).

Part of interest: The website of the Living Lab and in particular the participatory programs for promoting "Health with and for society".

Target groups: Policymakers, RPOs, Innovation Business, CSOs, Higher Education Institutions, Providers

→ **Link to the document**

78. CitieS-Health Toolkit "Putting Citizens's concerns at the heart of citizen science

Within the CitieS Health Project, citizens participate in defining research questions, designing and implementing studies, and analysing, interpreting, and communicating results. This document (Deliverable D5.2, 2019), describes the "CitieS-Health Toolkit", aimed to enable an interactive experience in designing a new brand collaborative bottom-up intervention or as an aid to existing participatory study, or for developing citizen science projects in urban environment and health. It provides a customised and interactive collection of adaptable instruments to empower researchers, individuals, and citizen groups that want to leverage the power of communities to solve common concerns and deploy actions for making the "world a better place to live in".

Part of interest: See in particular the part of the Toolkit, devoted to the Identification Phase of the Citizen Science project in this field.

Target groups: Scientists, Citizens, Policymakers, Business innovation, concerned with Health and environmental societal challenges

→ **Link to the document**

79. Prefer – Patient Preferences – Case study catalogue

PREFER is aiming at providing recommendations to support the development of guidelines for industry, Regulatory Authorities, and HTA bodies on how and when to include patient perspectives on the benefits and risks of medicinal products. Patient preferences can give information that is critical for developing medical treatments. PREFER is running patient preference studies in both academic and industry settings. This experience will provide a better understanding of what will be a recommended best-practice approach to patient-preference studies. But they can also tell us how

much risk patients think is acceptable for a given benefit. The methods to find out, or 'elicit' patient preferences are there, but decision-makers are not sure how to assess and use them. The PREFER Project is running three large clinical patient preference studies (including specific focus groups) in three disease areas: lung cancer, neuromuscular disorders, and rheumatoid arthritis. The resource contains the catalogue of the clinical patient preference studies implemented, made by adding to the PREFER portfolio, other clinical studies that cover different disease areas, methods, and research questions. Based on the case studies, PREFER is providing recommendations and guidelines.

Part of interest: The entire resource.

Target groups: RPOs, Professionals, Patients, CSOs, Providers, Innovation Business

→ **Link to the document**

80. FoTRRIS Report on co-RRI projects

This report is an outcome of the EU project Fostering a Transition Toward Responsible Research and Innovation System (FoTRRIS Project, Deliverable D3.1, 2018). It was selected for the CHERRIES Toolbox as a useful example of co-design of project based on co-RRI concept, and in particular as example of co-definition of needs in different areas. The document describes the activities carried out in 5 Co-RRI transition experiments in different European countries, by the implementation of workshops for system mapping; visioning; project concept design; status quo. One of the experiments concerned women with disabilities in Spain, and in particular about co-definition of needs (including health).

Part of interest: See in particular experiment 7 in Spain, from Pg. 136 to 147.

Target groups: Providers, Professional, Patients, CSOs, RPOs, Innovative business

→ **Link to the document**

81. The NewHoRRIzon Social Lab 7: Health, Demographic Change and Wellbeing

This Social Lab was established within the framework of the NewHoRRIZON. Its focus was on Responsibility in healthcare Research and Innovation. The Lab promoted the implementation of three real-life experiments from which gain insights into how a transformation towards an R&I system in health that is well-aligned with societal needs can be achieved. These pilots concerned: Enriching funding mechanisms (Pilot Action 1). Patient involvement in clinical service design (Pilot Action 2). Good practices of co-creation (Pilot Action 3). Within this last pilot action, characteristics of successful initiatives and instruments for engaging patients and citizens in agenda setting, research, and innovation were identified.

Part of interest: All the presentation of the Social Lab 7-health.

Target groups: Policymakers, Providers, Professionals, Patients, CSOs, Payers, Funding organisations, RPOs

→ **Link to the document**

82. SISCODE Toolbox for co-creation journey. Co-creation for society in innovation and science

The SISCODE Toolbox (2019) aims to facilitate the design and implementation of co-creation journeys for the integration of RRI principles within 10 SISCODE laboratories, focussing on better understanding and prioritisation of the particularities of each context. One of the laboratories is dealing also with health issues. The toolbox contains a selection of existing tools for the development of the design-based co-creation process from the context analysis, to reframe the problem, to envision and ideation of a solution, the development of a prototype and its experimentation in a real-world context. Among the co-creation experiences, see that of the Thess-Ahall Living Lab focused on the Challenge to fight loneliness in the ageing population using ambient assisted living solutions (https://siscodeproject.eu/thess-ahall/).

Part of interest: The entire document and in particular the part on "Reframe the problem", (Pp. 23-31), within which you can find the tool "Problem definition canvas" (Pp. 24-25).

Target groups: RPOs, CSOs, Innovation Business, Policymakers

→ **Link to the document**

83. Incorporating intersectional gender analysis into research on infectious diseases of poverty: a toolkit for health researchers

This resource is a WHO's Toolkit aimed at help researchers (in low and middle-income countries), to adopt an inclusive approach in research in health, providing guidelines and tools for incorporating gender and intersectionality analysis into research on infectious diseases of poverty. This Toolkit is articulated in 9 Modules. Module 1 provides an overview of the role and importance of gender and intersectionality for research on infectious diseases of poverty. Module 2 gives an overview of different approaches to incorporating an intersectional gender lens. Modules 3 and 4 describe intersectional gender analysis activities at the research design and development phase. Modules 5 to 9 describe various ways to use the intersectional lens in different kinds of research.

Part of interest: The entire document: in particular modules 3 and 4.

Target groups: RPOs, Business Innovation, Higher education institutions

→ **Link to the document**

B.3. Call for needs, Call for challenges, Open Innovation Call in health

Within this last sub-category, resources of interest for the RRI/demand-driven approach in health are included, with a focus on examples and materials concerning Phase 1 of the CHERRIES Pilots and on other examples of similar initiatives from which the CHERRIES experience took inspiration like the successful EU Project InDemand, or the Societal Challenge Innovation Platform.

CHERRIES Phase 1 was aimed at the identification of the territorial demand on which to base phase 2 of the territorial pilots in Örebro (Sweden); Murcia (Spain), and Cyprus and was articulated in the following main steps: a) Publishing of a territorial "Call for needs"; b) Collection and analysis of sectoral needs within each territory; c) Selection procedure of one "demand" per each region; d) Development of a Call for Solutions (see Section C of the Toolbox) in which to incorporate the sectoral demand and RRI principles).

In this sub-category are provided actual tools, like templates for the design of a Call for needs or Call for challenges (as it was labeled in various EU projects) in (digital) health, including the regional "Call for needs" recently published within the three Regions involved in the RRI experimentation in CHERRIES (available at this stage of implementation of the CHERRIES project). Besides the CHERRIES and the InDemand experiences, in this sub-category are also included other materials and tools concerning inspiring practices and experiences of the participatory and open innovation process for the identification of needs and unmet needs in health.

What follows are the resources of this subcategory.

84. The Regional CHERRIES Call for needs in Örebro, Cyprus and Murcia

The preparation and launch of a regional Call for Needs is the first step of the CHERRIES territorial pilots. The broadening of the process of need identification to make the process more inclusive and responsive to unmet needs and societal challenges in health at the territorial level is an important aspect of the CHERRIES approach. The set-up of a good need inventory is a necessary precondition for the definition of relevant needs and the design of the following process of co-creation for the innovative solution in each region. The open and bottom-up approach of the CHERRIES Calls for needs provided the opportunity to actively contribute, both to individuals and organisations, to key healthcare stakeholders of the R&I system and to individual citizens. On the website as examples are presented the three Call for needs prepared in CHERRIES context.

Part of interest: All the three "Call for needs".

Target groups: Providers, Professionals, RPOs, Innovation Business

→ Link to the document

85. InDemand – Demand-Driven Call for challenges in Digital health

The experience of the InDemand Project is an important reference for the development of the CHERRIES Call for needs. This document is an example of the Call for needs or Call for challenges published within that project. InDemand set up and tested a new co-creation model where healthcare organisations (Challengers) and companies (Solvers) co-develop digital health solutions, with the economic support of public regional funds managed by Regional funding organisations (Funders). The first phase of the model is focused on the identification by the challenger of unmet needs (challenges) identified with the involvement of healthcare professionals. In the links provided below, you will find info about the Call for needs launched in 2018 by the Navarra region.

Part of interest: See the challenges related to health and disabilities and those related to aging.

Target groups: Providers, Professionals, RPOs, Innovation Business

→ Link to the document

86. Social Challenges Innovation Platform (SCHIP)

Socialchallenges.eu is an open Platform on social Innovation, funded by EU H2020, which adopted a challenge-based innovation approach to solve societal and environmental local problems. Among the Platform objectives can be cited: supporting European stakeholders (public, private, non-profit) in defining and prioritizing social and societal challenges; encouraging a broad participation of social innovators, social entrepreneurs, start-ups, and SMEs to identify, co-develop and test concrete solution to these needs. The Platform was aimed at creating a social innovation marketplace, where Public Authorities, Private Companies, or Third Sector Organisations were able to post and give visibility to social and environmental challenges they wanted to solve. Different "Challenger owners" (public, private, NGOs, etc.) uploaded their social challenges and were supported by the project to find innovative solutions.

Part of interest: See, in particular, the challenges related to health and disabilities and those related to aging.

Target groups: Policymakers, RPOs, Innovation Business

→ **Link to the document**

87. PPIE Implementation Program – Pilot Call for Public & Patient Involvement and Engagement in Research 2020

Patient and Public Involvement and Engagement (PPIE) Programme, by Ludwig Boltzmann Gesellschaft (LBG), carries out research "with" or "by" patients and members of the public rather than "to", "about" or "for" them). PPIE aims to empower the public and people with lived experiences by involving them in research. Projects address patients' and the public's needs and embrace their knowledge from personal experience or practice during the different phases of the research cycle (from setting the agenda to interpreting data) and research governance. Based on this approach, LBG launch specific Calls for Public and patient involvement and engagement in Research.

Part of interest: See Section "Fund".

Target groups: RPOs, Providers, Patients, Innovation Business, CSOs, Professionals

→ **Link to the document**

88. Ances Open Innovation Initiative

The ANCES Open Innovation is an Initiative promoted by ANCES, Asociación Nacional de CEEI Españoles, focused on the identification of industrial needs and on the set up of call for solution to SMEs and innovation business able to address such challenges. On the website of the Initiative, there is a general presentation of the procedure and examples of the last 2020 Ances Call and the identification of technologic needs expressed by several enterprises, among which, for instance, that one published by Abbot Nutrición (Ances Open Innovation | ABBOTT).

Part of interest: The website of the Initiative and in particular the page concerning the Needs published in the ANCES Open Call 2020.

Target groups: Intermediary innovation organisations, Funding organisations, Innovation business, Start-ups, SMEs

→ **Link to the document**

89. Gendered innovations in Science, Health&Medicine, Engineering and Environment Live website

The "Gendered Innovations in Science, Health&Medicine, Engineering and Environment" is a project initiated by Stanford University in 2009. The goal of the project is to provide scientists and engineers with practical methods for sex and gender analysis. To match the global reach of science and technology, methods of sex and gender analysis were developed through international collaborations. The website contains several theoretical and practical resources concerning: methods of sex and gender analysis and checklist; case studies coming from different disciplines; intersectional design; policy recommendations and videos. A specific section of the website is devoted, among others, to the presentation of case studies that provides practical examples of how sex and gender analysis lead to gendered innovations in medicine. It is important to take into account and to integrate gender issues in innovation also in applying demand-driven and user-led/people-centric/open innovation process in healthcare.

Part of interest: The entire website. In particular, see the sex and gender analysis section and the section on case studies in health and medicine.

Target groups: Providers, RPOs, Innovation business, Higher education institutions

→ **Link to the document**

C. CO-CREATION FOR THE INCLUSION OF SOCIAL VALUES IN THE DESIGN, DEVELOPMENT, AND TEST OF RESPONSIBLE INNOVATION SOLUTIONS IN HEALTH

This category contains resources for supporting the innovators and all the different stakeholders involved in the co-creation process of the design, development, and test of responsible innovation solutions in health, able to address the needs identified in the previous phase and to incorporate social values. The category is related to the crucial phases of the RRI bottom-up demand-driven innovation approach of CHERRIES: the Call for solutions and the co-creation of the solution.

In this framework, the adoption of an inclusive approach is tied to two important pre-requisites that are present in all the phases of CHERRIES approach, i.e., citizen and patient engagement in research and innovation activities and territorial stakeholder involvement. In fact, the Call for solutions, the selection of the "solver" provider, and the co-creation of innovative solutions to healthcare problems and needs require:

- To promote a close relationship among challenger owners, solution providers and users, citizens, patients, and other relevant stakeholders
- To adopt an inclusive approach, able to include different views, needs, and experiences including also those of disadvantaged groups
- To be able to develop proactive management of new technologies so as to identify risks and develop an ethically adequate response in a transparent, open, and accessible way for everyone
- To consider societal and ethical aspects from the beginning of the innovation process
- To consider the advantages of a demand-driven approach.

A challenge in CHERRIES is also related to the integration of the RRI keys (gender, public engagement, ethics, science education, open access, science governance) and of the RRI dimensions (anticipation of possible risks, inclusion of stakeholders and citizens, reflexivity on the adopted approach, responsiveness to unexpected impacts or societal needs and expectations) in each step.

The resources collected here provide examples, practices, methods, and tools in this regard, and in particular: how to prepare, launch and implement a Call for solutions; how to promote and implement an effective engagement of stakeholders from the beginning of the process; how to involve actively citizens and patients in co-creation process; how to start a real co-creation process; how to integrate societal and ethical aspects in the co-design process.

In this framework, the resources are organized in the following five subcategories:

C.1. Call for solutions for addressing needs and challenges
C.2. The engagement of patients, citizens, and the public in innovation and research
C.3. Engagement and mobilisation of stakeholders (different from citizens/public) in research and innovation activities
C.4. Co-creation of the solution
C.5. Legal, ethical, and privacy requirements in co-creation research and innovation.

C.1. Call for solutions for addressing needs and challenges

This subcategory contains resources describing the process of implementing a Call for solutions adopted by various projects based on a demand-driven innovation approach. The Call for solutions for identified needs is a form of a Pre-Commercial Procurement process. The idea is to promote the best possible matching between specific needs or challenges with the best solution available.

The process for the design and launch a Call for solutions might include different steps such as: identification of the requirements for participation and the evaluation criteria; preparation of the Call; the launch of the Calls for solutions, able to solve specific need or challenge identified in the previous step and its dissemination in an open and transparent way; set up the committee for selection; selection of the solution; communication of the winner solution; contract agreement and payment. The entire process is presented below through several useful resources.

This subcategory includes also other resources in which the elements of RRI have been integrated as award criteria in call for grants in different fields of science and technology research by funding organizations such as VINNOVA or the NWO, or call for proposals on Citizen science. In these cases, RRI dimensions have been included as mandatory criteria of the proposals and their implementation.

In CHERRIES project the phase devoted to the Call for solutions includes the following four steps: 1. preparation; 2. publication; 3. evaluation; 4. granting and signature of the grant agreement and payment.

What follows are the resources to implement a call for solutions.

90. CHERRIES call for solution

At the beginning of January 2021, the CHERRIES Project is launching in the three territories of Örebro (Sweden), Murcia (Spain), and Cyprus the Call for solutions, mainly addressed to SMEs, Start-ups, and innovators able to co-create in a participative way a solution to the needs identified in the previous step. The text of the Call contains the selection criteria of the proposal, the template to be filled by the participants, and information on the way to participate and timing. The launch of the Call is being accompanied by a communication campaign and the organisation of meetings in the three territories.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Innovation Business, Providers, Start-ups

→ **Link to the document**

91. Social Challenges Innovation Platform

Socialchallenges.eu is a Platform aiming at creating a marketplace where actual social challenges can meet powerful and innovative solutions, where Public, Private and Third Sector Stakeholders can upload social and environmental challenges to receive innovative solutions from European innovators, start-ups, and SMEs.

Part of interest: See in particular the challenges related to health and disabilities, and those related to aging.

Target groups: Policymakers, RPOs, Innovation Business, CSOs

→ **Link to the document**

92. Social Challenges Innovation Platform – Call for grants

This is the text of the open Call for solutions Platform including eligibility criteria, calls details, and evaluation criteria set up the Social Challenges Innovation Platform.

Part of interest: The entire document.

Target groups: Policymakers, Providers, Professionals, Patients and CSO, Payer, RPOs, Innovation Business

→ **Link to the document**

93. Social Challenges Innovation Platform – Template for submission of solutions

This is the template for the submission of solutions defined and used in the Social Challenges Innovation Platform.

Part of interest: The entire document.

Target groups: Innovation business, RPOs

→ **Link to the document**

94. Social Challenges Innovation Platform – Call for grant: Guide for applicants

The document contains the instructions to apply for solutions and describes the functioning of the platform used by the Social Challenge Innovation Platform project in the 2nd cut-off date, in 2018. Social Challenges Innovation Platform has foreseen two elements in the call for solution: Value proposition for Challenge Owners and Solution providers.

Part of interest: The entire document.

Target groups: Innovation Business, RPOs, Providers, Professionals

→ **Link to the document**

95. Evaluation procedures for challenge owners

The resource is the Matrix set up and used by the Social Challenges Innovation Platform Project (Deliverable D2.3) to assess proposed solutions to a specific challenge.

Part of interest: The entire document.

Target groups: Providers, Professionals, Patients, RPOs, Innovation business

→ **Link to the document**

96. InDemand Open Call for Company

This document is an example of an Open Call for companies for co-creation of digital health solutions to challenges identified by health professionals, published within the framework of the InDemand Project which is a reference experience of demand-driven innovation for CHERRIES too. InDemand set up and tested a new co-creation model where healthcare organisations (Challengers) and companies (Solvers) co-develop digital health solutions. The first phase of the Model is focused on the need identification by the Challenger (Healthcare organisation) by the launches of a "Call for challenges" in several European regions. The second phase of the Model is the launch of the Call for solution, which is referred to the link, regarding the call launched in Murcia in 2019, containing the

description of the 4 challenges selected among the around 60 challenges identified by health professionals within the SMS-Servicio Murciano de Salud (Spain).

Part of interest: The entire resource.

Target groups: Providers, Professionals, RPOs, Innovation Business

→ **Link to the document**

97. InDemand – Calls 2018 for companies to tackle health challenges together with healthcare professionals in Murcia

These are the materials defined and used by InDemand Project in 2018 in Open the Call for companies for solution in Murcia to solve health issues and challenges identified by healthcare professionals (text of the open Call and the related document as application forms, guide for applicants, administrative documents, etc.).

Part of interest: The entire document.

Target groups: Innovation Business, RPOs, Providers, Professionals, Start-ups

→ **Link to the document**

98. InDemand Guide for Applicants (6th in Demand Open Call – Paris 2nd)

The resource includes the Guide for applicants of the InDemand project set up and used in the 6th Open Call Paris 2nd for solutions and the other documents related to the call (template to be used, declarations to be signed, etc.). In particular, the Guide describes the challenges to consider, the criteria for applying, the evaluation criteria, the process of selection, the co-creation activities.

Part of interest: The entire document.

Target groups: Providers, Professionals, RPOs, Innovation Business

→ **Link to the document**

99. Ances Open Innovation

It is an initiative ANCES Open Innovation focused on the identification of need/challenge and a call for solution to SMEs and innovation businesses able to address such need/challenge. The website presents also the form to be filled for participating in the initiative ANCES Open Innovation. The tool is in Spanish.

Part of interest: The entire website and in particular Section "Participar".

Target groups: Policymakers, RPOs, Innovation Business

→ **Link to the document**

100. INSPIRES Ingenious Science shops to promote participatory innovation, Research and Equity in Science

The present resource (Deliverable D4.1. "Open Call results", 2019) illustrates the aim and the procedure implemented for the launch of an Open Call, addressed to Science Shop entities, within the framework of the InSPIRES project. This Call was aimed at providing financial support for the implementation of participatory research projects focused on RRI in health and environmental issues. InSPIRES brings together practitioners and experts to co-design, jointly pilot, implement, and roll-out innovative models of participatory research projects for the Science Shops target. The InSPIRES models integrate RRI, Open Science, and Impact Evaluation to open the research process up in a more strategic way to civil society and other stakeholders.

Part of interest: See in particular the Annex 1 "Terms and conditions of the Open Call".

Target groups: Science shops and RPO's, Policymakers, CSOs, Innovation business, Citizens/Patients

→ **Link to the document**

101. VINNOVA – Challenge Driven Innovation

Challenge Driven Innovation (CDI) is a research and innovation-funding programme developed by Vinnova's Swedish Innovation Agency to fund collaboration in research and innovation that address societal challenges. The program foreseen inclusion of different actors in the project; supports a problem-oriented and demand-driven approach that necessitates anticipation and reflection; encourages learning by doing and responsiveness and capacity of changing and adapting. Gender equality is an important element of CDI.

Part of interest: The entire document.

Target groups: Payers, RPOs, Innovation Business, Policymakers

→ **Link to the document**

102. Rewarding RRI. A case study collection of the European Foundations Award for Responsible Research and Innovation 2016

This document, produced by the King Baudouin Foundation and the European Foundations Award for RRI (EFARRI), describes the Award for RRI 2016 by a call for projects on RRI in the European Research Area. The EFARRI aims to identify research groups that have successfully incorporated methods to align research with the needs of society and contributed towards the development of a smart, inclusive, and sustainable society. The document describes 8 steps of the Award, the content of the call for project, the selection procedure, the composition and work of the Jury, the Award Ceremony, and dissemination activities. The Award incorporates RRI dimensions among the criteria for selecting the projects.

Part of interest: The entire document and in particular Pp. 6-14 for the methodology of the Award. The document presents also the 15 RRI finalist practices.

Target groups: Payers, RPOs, Innovation Business, CSOs, Higher Education Institutions, Policymakers

→ **Link to the document**

103. NWO – Innovative Medical Devices Initiative

The NWO – Dutch Council Research in the framework of its RRI program, is carrying out from 2018 a series of initiatives using RRI dimension as criteria for a call for proposals aimed at promoting interdisciplinary collaboration between researchers from the humanities, natural sciences, engineering, and social sciences. One of these initiatives is IMDI Innovative Medical Devices Initiative. IMDI is a strategic public-private partnership that was established in 2010. It specifically focuses on the development and application of medical technology that tackles the increasing shortage of healthcare personnel and safeguards accessibility to healthcare. NWO Responsible Innovation Programme is an important component in various IMDI calls paying special attention to social and ethical issues.

Part of interest: The entire document.

Target groups: Payers, RPOs, Innovation Business, Policymakers

→ **Link to the document**

104. Crew Call 2019 for Entrepreneurial initiatives concerning technological devices and solutions for disability

CREW, Codesign for REhabilitation and Wellbeing, is a research project developed by Fondazione Cariplo with the scope to create innovative technological solutions in the motor and cognitive rehabilitation field and aimed to the facilitation of the social inclusion of people with permanent, temporary, or age-related disabilities. CREW was shaped on the European model of RRI, using co-design as a methodology to express and identify the needs and find the related solutions. This was carried out by five project laboratories dedicated to: sport and disability, school integration and autism, neuro-motor paediatric disabilities, ambient living to maintain life autonomy, and for a new life autonomy. The resource is in Italian.

Part of interest: The entire document.

Target groups: Innovation business, RPOs, Patients, CSOs, Providers, Professionals

→ **Link to the document**

105. Open Healthcare Map

This resource, set in the framework of CAREABLE project (Deliverable D2.1), presents a selection of 45 best practices in 9 fields of application in Open Healthcare, sourced from online repositories. The Open Healthcare map shows various existing platforms where makers share open-source solutions. It shows a variety of complexity and relevance of repositories online.

Part of interest: See the entire document.

Target groups: Providers, Professionals, Patients, CSOs

→ **Link to the document**

C.2. The engagement of patients, citizens and the public in innovation and research

Citizen, patient, and public engagement is an important and basic element in each RRI bottom-up demand-driven approach, including CHERRIES. Such a wealth of different knowledge and experiences represent a resource that needs to be managed and used carefully. An important experience of public engagement is that of Citizen science projects and activities, in which citizens are involved in the research cycle in different fields and at different levels, as contributors only in the collection of data, collaborators (not only in the collection of data but also in helping to refine project design, to analyse data, or to disseminate findings), or active participants in defining and implementing co-created projects in all its phases.

The area of public engagement concerns the involvement of individual citizens. Public engagement might be implemented with different levels of engagement: from the simple level of consultation by a public dialogue and deliberation, up to collaboration in designing, implementing, monitoring, and assessing projects, innovations, policies, etc.

In CHERRIES public engagement activities are being implemented in different phases of the project and in particular in the deployment of the three pilots in Örebro (Sweden); Murcia (Spain), and Cyprus, with particular reference to the need identification and the co-creation stages. In this framework, one of the challenges for organizations that implement the pilots is to start a reflection about the possibility to institutionalise the involvement of citizens and patients also by the creation of a permanent space for public engagement.

This subcategory provides tools, approaches, and experiences on why and how to engage the general public and citizens in research and innovation activities, including healthcare; which are drivers and obstacles; which are the precautions that have to be taken into consideration, etc. The resources provide also answers to some important issues to take into consideration in implementing citizen engagement, such as how to reach, attract the interest and involve individual citizens; their representativeness; why they might be interested to participate; which are common obstacles and problems to be taken into consideration.

What follows are the resources of this subcategory.

106. EDGE tool

This is the interactive tool to assess the institution's support for public engagement, provided by the National Co-ordination Centre for Public Engagement. Besides the tool, the website contains also resources on public engagement.

Part of interest: The entire document.

Target groups: Policymakers, Providers, RPOs, Business Innovation, High Education Institution

→ **Link to the document**

107. PE2020 Toolkit on public engagement with science and technology

The aim of the toolkit, set up in the framework of the EU project PE2020, is to provide easy, rapid and guided access to practical and theoretical knowledge on strategies and approaches to public engagement with science. The toolbox is composed of four sections: section A strategic framework; section B methods and tools; section C, institutional anchorage; section D, societal anchorage. In particular, part B contains inputs and resources about: types of public engagement and connections with organisational processes; designing PE initiatives; implementing PE initiatives; monitoring and evaluation.

Part of interest: See also PE2020 Catalogue of Public engagement initiative and the Inventory of PE initiatives.

Target groups: Policymakers, Patients and CSOs, Providers, RPOs, Innovation Business, Intermediaries

→ **Link to the document**

108. A practical guide for stakeholder engagement in future and emerging technologies

This is a practical guide set up by the Project EFFECT for communication and public engagement activities on the future and emerging technologies (2018). It contains the description of 10 methodologies for public participation in science and 4 methodologies for younger involvement and a form on evaluation procedures.

Part of interest: The entire document.

Target groups: Policymakers, Patients and CSOs, Providers, Payers, Intermediaries, RPOs

→ **Link to the document**

109. Methodology for citizens participation

The PROSO Project aims at advancing insights into factors that influence the engagement of two types of societal actors, namely third sector organisations (TSOs) and non-organized citizens. This document deals with the engagement of the latter. In particular, it contains a description of how to design a citizen panel. The resource (Deliverable D4.1, 2016) is also useful for those stakeholders engaged in promoting the participation of single citizens.

Part of interest: The entire document.

Target groups: RPOs, Providers, Professionals, Patients, Citizens, CSOs, Policy Makers, Higher Education institutions

→ **Link to the document**

110. Engage2020 Action Catalogue

The catalogue is an online platform, and it is one of the products of Engage2020 Project. The catalogue gives an overview of 57 methods that can be used for engaging society in research and innovation. It contains detailed factsheets on all the collected methods, providing information such as objectives, background, different levels of research and innovation activity, and examples of use. The catalogue has a search engine. The content of the catalogue has been also published in the Deliverable D3.2. "Public engagement methods and tools".

Part of interest: Each user might choose the method of interest.

Target groups: Policymakers, RPOs, Innovation Business, CSOs, Higher Education Institutions, Payers, Providers

→ **Link to the document**

111. The rise of Citizen Science in Health and Biomedical Research

Citizen science models of public participation in scientific research represent a growing area of opportunity for health and biomedical research, as well as a new impetus for more collaborative forms of engagement in large-scale research. However, this also surfaces a variety of ethical issues that both fall outside of and build upon the standard human subjects concerns in bioethics. This article (by Wiggins, Wilbanks, 2019) provides background on Citizen science, examples of current projects in the field, and a discussion of established and emerging ethical issues for Citizen science in health and biomedical research.

Part of interest: The entire article.

Target groups: RPOs and Scientists, CSO and Citizens, Policymaker, Business innovation

→ **Link to the document**

112. Citizen science provides a reliable and scalable tool to track disease-carrying mosquitoes

This article (by Palmer et al., 2017) is focused on the usefulness of Citizen science in health. Traditional surveillance tools are limited by jurisdictional boundaries and cost constraints. The article shows how a scalable Citizen science system can solve this problem by combining citizen scientists' observations with expert validation and correcting for sampling effort. The system described in this article provides accurate early warning information about the Asian tiger mosquito (Aedes albopictus) invasion in Spain collected using Citizen science, providing data well beyond those available from traditional methods, and vital for public health services.

Part of interest: The entire article.

Target groups: RPOs, CSOs

→ **Link to the document**

113. Toolkit for patient organisations on patient empowerment

This is the Toolkit drafted by the European Patient Forum. Starting from a definition of patient empowerment and related concepts, the document provides key advocacy tools of patient empowerment.

Part of interest: The entire document.

Target groups: Providers, Professionals, Patients, CSOs

→ **Link to the document**

114. Paradigm Patient Engagement Toolbox

This is a resource made by the PARADIGM Project. The Toolbox contains co-created recommendations, tools, and relevant background information to make patient engagement in medicines development easier for all. In particular, the Toolbox is articulated in three main areas: planning patient engagement; conducting patient engagement; reporting, and evaluation. The Toolbox includes the following resources: evaluation and monitoring framework; code of conduct for patient engagement; guidance on patient dialogue in the early stage of patient engagement; guidance on managing competing and conflicts of interest.

Part of interest: The entire toolbox.

Target groups: RPOs, Business Innovation, Providers, Professionals, Patients, CSOs

→ **Link to the document**

115. The Involvement Matrix – Involvement of patients in project and research – Practical Guide

This Matrix (developed by Smits, Klem, and Ketelaar, Centre of Excellence for Rehabilitation Medicine Utrecht) has been developed to promote collaboration with patients (from the age of 12) in projects and research. The Guide contains info about the 'what' (roles, phases, and activities of patient involvement in a project) and the 'how' (principles for having dialogues and concrete recommendations for using the Matrix). The Matrix identifies 6 roles: listener; co-thinker; advisor; partner, decision-maker. The Matrix singles out three phases: preparatory phase; execution; implementation.

Part of interest: The entire document.

Target groups: Policymakers, Providers, RPOs, Patient, Professionals

→ **Link to the document**

116. An overview of critical decision-points in the medical product lifecycle: where to include patient preference information in the decision-making process?

The aim of PREFER Project (to which this resource is connected) is to strengthen patient-centric decision-making throughout the life cycle of medicinal treatments by developing expert and evidence-based recommendations on how patient preferences should be assessed and inform decision making. The project is identifying 15 critical decision moments in which it is important to include patient preferences in the medical product lifecycle. Patient preference (PP) information is currently not routinely considered one of the requirements for decision-making. The resource (by Whichello et al., 2020) proposes a road map for including patient preferences in the life cycle of medical treatment.

Part of interest: The entire article.

Target groups: RPOs, Innovation Business, Patients, Professionals, Providers

→ **Link to the document**

117. Involving Patients in Research? Responsible Research and Innovation in Small- and Medium-Sized European Health Care Enterprises

This is an article (by Jordanou, 2019) on the obstacles met by SMEs in involving the patient in research. This issue is examined on the basis of 18 in-depth interviews with private healthcare industry representatives from across Europe in companies focusing on developing medical device technology. Findings suggest that SMEs are reluctant to undertake research involving patients, especially in the early stages of the research and innovation process. For some SMEs, this is due to concerns about the dangers of raising expectations they cannot meet, while for others the main

concerns are increasing costs and producing less competitive products. Recommendations in this respect are also provided.

Part of interest: The entire article.

Target groups: CSOs, Innovation business, Patients, RPOs

→ **Link to the document**

118. Multiact Guidelines for patient engagement

The Guidelines (set up in the framework of Multiact Project) propose a roadmap to capture the 'experiential knowledge' of patients, to better understand how to draw on their experience and use the experience constructively for co-creation purposes. The roadmap consists of four activities: setting up an Engagement Coordination Team with trained figures; selecting the research steps where patient engagement is instrumental to meet the project's mission/agenda; developing an engagement plan for each research identified steps; selecting the indicators to be used to measure the success and effectiveness of this engagement. 7 steps for patient engagement are foreseen: Translation to community; Setting research priorities; Breaking down boundaries between patients and stakeholders; Research design and plan; Research evaluation; Steering institutions; Research execution.

Part of interest: The entire document.

Target groups: Policymakers, Providers, Professionals, Patients, RPOs, Innovation Business

→ **Link to the document**

119. Social media Toolkit for healthcare professionals. Spreading authoritative information online

This a Guide drafted by the European Commission on the use of social media on health and vaccination communication, particularly relevant in the context of Covid-19 pandemic. The Toolkit provides suggestions on how to use social media for correct information and communication on vaccination. In particular, it suggests 7 steps for engaging and starting communication activities on health issues. Communication is a basic element of public engagement.

Part of interest: The entire document.

Target groups: RPOs, Professionals, RPOs, Innovation Business, Media

→ **Link to the document**

120. IMI Innovative Medicines Initiative

IMI is a Public-Private Partnership initiative, aimed at improving health by speeding up the development of, and patient access to innovative medicines, particularly in areas where there is an unmet medical or social need, and by facilitating collaboration between the key players involved in health research. Citizens are invited to participate in the PP IMI by becoming a partner in a project or member of project advisory committees or associate partner or by proposing ideas and suggestions. IMI launches calls for proposals and publishes draft topics texts on future topics. The calls require the participation of citizen and patient organisations.

Part of interest: See the general overview and the call documents.

Target groups: RPOs, Innovation business, Policymakers, CSOs, Patients, Payers, Providers, Professionals, Intermediaries

→ **Link to the document**

121. A short guide to successful patient involvement in EU-funded research

In the framework of the Project U-BIOPRED has been draft the guidelines on successful involvement of patients in the EU project. U-BIOPRED Project is aimed to speed up the development of better treatments for patients with severe asthma. Patients (including also caregivers and patient organisations) were involved in the consortium and participated with their experiences to the outcomes of the Project. Patient involvement can optimise the ethics, relevance, accountability and transparency, communication, promotion, and implementation of research outcomes. Patient involvement groups might have different forms, all able to bring their own experience to support a project.

Part of interest: The entire document.

Target groups: RPOs, Innovation business, Providers, Patients, CSOs

→ **Link to the document**

122. My brain Book: A case study on Responsible research and innovation and communication technology for ageing people

The case study (by Navda, 2018), linked with Orbit project, describes how people with dementia and their carers have been involved in several different and creative ways in the initial development and testing of a working prototype of a computer-based planning tool for people with dementia and their carers. The tool, called My Brain Book, aims to record information about the person with dementia in order to produce a care plan that is created jointly between the person with dementia and their families and shared easily with a range of professionals. Engagement activities included: a parallel priority-setting event, focus groups, involvement in design workshops, and testing of the prototype.

Part of interest: The entire document. It contains also a description of the way by which people with dementia and their family and caregivers have been involved.

Target groups: RPOs, Providers, Professionals, Patients, CSOs

→ **Link to the document**

123. ¡Pasa la voz!

¡Pasa la voz! is a raising awareness project about Chagas disease to improve access to diagnosis and treatment. It was among the finalists of the EFARRI-European Foundations Award for RRI in 2016. EFARRI aims to identify research groups that have successfully incorporated methods to align research with the needs of society and contributed towards the development of a smart, inclusive, and sustainable society. The project carried out by the ISGlobal team foresees the involvement of the different stakeholders since the beginning of the activities.

Part of interest: The entire document.

Target groups: Providers, Professionals, Patients, CSOs

→ **Link to the document**

124. RRI case studies – the case of GlucoTelTM

This case study is focused on telemedical applications in the area of diabetes care through the case of GlucoTel™, a telemonitoring system developed by BodyTel™. It links the company's activities to aspects of RRI such as addressing societal challenges, stakeholder engagement, legal requirements, and open access. BodyTel™ engages stakeholders such as patients and caregivers during its development processes to improve the treatment of chronic diseases and contribute to a higher quality of life for patients. These were the 5 stakeholder groups considered: patients & family, caregivers & medical advisers, health insurance companies; medical technological & pharmaceutical companies; integrators of sensors and services.

Part of interest: The entire document.

Target groups: Patients, Providers, Professionals, RPOs, Innovation Business

→ **Link to the document**

C.3. Engagement and mobilisation of stakeholders in research and innovation activities

Stakeholder engagement and mobilization represent a fundamental aspect in each RRI bottom-up demand-driven innovation approach, including CHERRIES, which started with an exercise of stakeholder mapping and identification (see Category A). Some methods and tools presented in the subcategory C2 on public engagement and in subcategory B2 on participatory research are also useful for stakeholder engagement. This subcategory is also tied with subcategory A3 on partnerships and territorial coalitions.

Nevertheless, there are some specific issues characterising stakeholder engagement (beyond citizens/public) and mobilisation to be taken into consideration. Among those specific issues, the following can be mentioned: the need to adopt an inclusive approach, involving also those actors that usually are not taken into consideration, such as CSOs (as organisations); the definition of the criteria for choosing the stakeholders; the analysis of diverse motivations driving each stakeholder; the power of each stakeholder and the dynamics of power (unbalanced) involved in multi-stakeholder engagement and dialogue (for example between policymakers and CSOs). Moreover, managing such diversity requires to promote mutual learning initiatives, to establish a common language, to promote trust, and to overcome possible stereotypes.

In this framework, the resources, mainly provided by EU projects, contain information and guidance about problems, obstacles, and solutions in stakeholder engagement.

In CHERRIES stakeholder dialogue, engagement and mobilisation is a crucial aspect and a cross-cutting component of each phase of CHERRIES (from framing the scene of the pilots, to the need identification, from the Call for solutions to the co-creation of the solution and its adoption). In this case, one of the challenges for the organisations promoting the pilot and for the innovators steering the co-creation of the solution is how to institutionalise and create a permanent space for stakeholder dialogue and engagement in the governance of the healthcare system or innovation practices and procedures.

What follows are the resources of this subcategory.

125. Guide on public engagement and co-creation

The Guide (drafted in the framework of TeRRIFICA project, Deliverable D4.1., 2019) describes tools, activities, and methodology for stakeholder engagement and co-creation for climate change, on the basis of the pilots carried out by TeRRIFICA. In particular, the focus is on how addressing possible conflicts, challenges on public engagement. The document might be useful for stakeholder mapping and engagement (section A) and for co-creation activities (section C). Each part contains examples based on TeRRIFICA experiences.

Part of interest: See section 2.

Target groups: Policymakers, CSO, RPOs, Innovation business

→ **Link to the document**

126. EUSEA-European Science Engagement Platform

Repository of toolkits on public engagement and science communication set up by EU projects on public engagement, citizen engagement, and co-creation. The resources of this platform might be useful in all the phases of implementation of CHERRIES approach.

Part of interest: The entire platform.

Target groups: Policymakers, RPOs, Innovation business, Higher Education institutions, CSOs, Payers, Providers

→ **Link to the document**

127. SISCODE Co-design for society in innovation and science – Activities pool for co-creation labs and open days

The document describes a pool of activities for co-creation labs and Open Days (SISCODE Project, Deliverable D7.3, 2019) that labs can use or take inspiration from to create an interactive and engaging programme for local audiences. The activities selected and described are: 12 ice-breakers, 14 dialogue activities, and 9 engagement activities.

Part of interest: The entire document.

Target groups: Policymakers, Innovation business, RPOs, CSOs

→ **Link to the document**

128. Engaging Society for Responsible Research and Innovation. Lowering Barriers, Innovating Policies and Practices

This is a PROSO Project support tool for promoting engagement of citizens and third sector actors in research and in research and innovation policy. In particular, the document identifies lowering barriers and innovating policies and practices for addressing such barriers, with different options. These are six barriers: lack of relevance; lack of impact; lack of trust and critical views of others; lack of knowledge and skills; lack of time and finances; and lack of legitimacy. Different options are provided for different actors, namely policymakers and governmental agencies, research funding organisations and research councils, public and private research organisations and (other) engagement performing organisations, and third sector actors.

Part of interest: The entire document.

Target groups: Policymakers, CSOs, Patients, RPOs, Innovation Business, Payers

→ **Link to the document**

129. Act on Gender Community of practices co-creation toolkit

The document was drafted in the context of the ACT for gender equality Project Community of practices (CoP). The toolkit describes 20 different participatory methods, online methods, and visual methods. It shows how and which tools and methods the CoPs might operate, develop, implement gender equality plans (GEP), gender equality (GE) measures and activities, and facilitate institutional change in relation to GE in HE and R&I. Such methods might be useful in implementing the 6 steps for the process of setting up, implementing, monitoring and evaluating GEPs.

Part of interest: The entire document, and in particular chapters #7, #8 and #9.

Target groups: RPOs, Higher Education Institutions, CSOs, Payers, Innovation Business

→ **Link to the document**

130. Engagement strategy & documentation of events

This document shows the detailed stakeholder mapping and the engagement strategies process that Careables project (Deliverable D1.1, 2018) has applied.

Part of interest: See in particular section 5.5.

Target groups: Providers, Professional, Patients, CSOs

→ **Link to the document**

131. Sparks Handbook for participatory activities

SPARKS is an awareness-raising and engagement project to promote RRI across 29 European countries (EU members plus Switzerland and the UK). This resource focused on participatory activities, and it is articulated in the following parts: rethinking innovation together; innovative participatory activities; capturing the scene (guidelines to plan of the work, establishment of local partnerships; different kinds of activities, templates for the organizers). The resource contains also experiences and practices.

Part of interest: See the part on Guidelines for implementing innovative participatory activities on RRI (science cafés, pop-up Science Shops, incubation activities, and scenario workshops).

Target groups: Policymakers, RPOs, Patients and CSOs, Innovation business

→ **Link to the document**

C.4. Co-creation of the solution

This subcategory is focused on the process by which the solver (i.e., the innovator, including also ICT and legal experts, designers, etc.) and the owner of the need (that is the group of stakeholders that proposed the selected need, including representatives of the healthcare organization, professionals, CSOs and patient organisations, etc.) co-create the solution with the support of the promoter.

Even if co-creating and co-designing innovative products, services, or policies might require more time, it produces some important effects, such as, for example: increasing the legitimacy and effectiveness of design and implementation of measures and policies with respect to its goals; reducing the risk of failure; avoiding making wrong decisions based on assumptions and unnecessary waste of time, money and energy; facilitating the access to the market of the product/innovation.

Some elements of RRI are present in the co-creation process and for this reason, some EU projects (like for example SISCODE, FoTRRIS, Scalings) promote a co-creation approach in embedding RRI in research organisations or SMEs, while the EU is promoting a co-creation approach in designing policies and services. In CHERRIES, co-creation is at the core of the three pilots that are being implemented in the three regions of Örebro (Sweden); Murcia (Spain), and Cyprus. Generally speaking, the co-creation process will include: establishing the co-creation team; defining the work programme of the co-creation activities; managing the contractual and financial aspects; implementing the work plan, assuring the participation of all the involved parties; monitoring the implementation plan, and support the co-creation team.

In particular, this subcategory contains, also on the basis of EU projects (like SISCODE or FoTRRIS), resources on how to prepare, design, and implement co-creation activities, examples of co-creation practices (like living labs, and so on), training kit modules on co-creation, toolkits on co-creation and co-design.

What follows are resources useful to "co-creation of the solution".

132. Careable training kit

This training kit, set up in the framework of Careable project, provides all the practical information for people that need to set up an event series and guide the process by the organisation of a prototyping series. It gives guidelines and tips on: how to find partners to cooperate with, how to gather a diverse group of participants, how to set up the different stages of the prototyping series, how to document the overall process and resulting products on Careables.org. This is a useful tool to create a fruitful environment in which organisations can successfully work together and develop freely and design solutions, based on the needs of individual patients.

Part of interest: See in particular the Appendix #13 "Healthcare co-design toolkit".

Target groups: Providers, Professionals, Patients, CSOs

→ **Link to the document**

133. The co-creating welfare training course

The Co-Creating Welfare Training Course aims to enable professional practitioners within the health and social welfare sector to create, implement, and evaluate co-creating processes with the citizens benefitting from the welfare services of their organisation. The Training Course is built around 4 training themes that are: Creating a common understanding of co-creation; Initiating the co-creation process through collaborative problem formulation; Managing the co-creation process; Dissemination and communication of the co-creation process and its results. There is also an online Tool that contains a report with all the material of the training course, videos, the deck of co-creation tool cards. Different tools are proposed that might be used for different a kind of activities: brainstorming; problem identification; design solution, etc.

Part of interest: The entire web tool.

Target groups: Providers, Professionals, Patients and CSOs

→ **Link to the document**

134. The role of need in open and user-led innovation approaches in healthcare

The first episode of the "CHERRIES webinar series 2020 Exploring responsible healthcare ecosystems in Europe" was devoted to a reflection on "Regional innovation ecosystems for healthcare", with the contribution of Wouter Boon (University of Utrecht) and Myriam Martin (Ticbiomed; InDemand Project). During the webinar was discussed the role of users in the healthcare innovation process; how demand/need driven innovation approaches can result in improved healthcare ecosystems; and which are the key issues to be considered when launching a co-creation process.

Part of interest: The entire webinar.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

135. CRISH Training course

CRISH (Co-CReating Innovative Solutions for Health) main objective is to bring together key stakeholders of the health sectors, including patients, for learning how to co-create innovative processes, products or services for health improvement and jointly anticipating emerging trends on health and ageing. CRISH is a short course providing knowledge, skills, and tools on patient experience methodology (XPA), responsible research and innovation components (RRI), entrepreneurship elements (ENT), and reciprocity and co-design methods (RcD) to a variety of health stakeholders. CRISH trains health professionals, home caregivers & researchers in identifying, with patients, critical points for future research, re-design of clinical services through the patient experience methodology, and identify ideas to pursue the development of innovative solutions.

Part of interest: All the links.

Target groups: Providers, Patients, Professionals, RPOs, Innovation business.

→ **Link to the document**

136. Empowering Women Entrepreneurs in health innovation

WE Health is an EIT Health Campus programme designed to enhance the participation of women in health innovation and entrepreneurship. WE Health empowers female health innovators by providing training specifically tailored to their needs, offering inspiration and support to help them advance in their professional careers. WE Health also aims to raise awareness of the positive economic and social impact of gender diversity in health innovation, while generating new ideas that promote innovation across the entrepreneur community in a more balanced way.

Part of interest: The entire platform.

Target groups: Innovation Business, RPOs, Higher Education Institutions, CSOs

→ **Link to the document**

137. InDemand: Deman driven eHealth co-creation and business support

This is the Deliverable D5.1 of the InDemand Project describing the co-creation activities and business support in the three regions of Murcia (Spain), Oulu (Finland), and Paris. In particular, the Report describes the third phase of InDemand, in which Challenger and Solver develop together a new healthcare solution. Solver receives business advice from the Supporter. These activities facilitate the co-creation between Challengers and Solvers as well as the delivery of business support. At the end of co-creation, Funder oversees the Evaluation and Payment process. This phase is organised in the following steps: preparation; management of co-creation; management of business support; evaluation and payment; assessment and contribution to the knowledge base.

Part of interest: The whole document.

Target groups: Innovation business, RPOs, Providers, Professionals, Patients, Payers

→ **Link to the document**

138. InDemand model for co-creation of solution (among Challengers, Funders, Solvers, Supporters)

The web tool describes the demand-driven co-creation approach used by InDemand Project in the three pilots in Spain (Murcia Region), Finland (Oulu Region), and France (Paris Region) and within InDemand Community, and by which is possible to access various resources. According to this model, healthcare organisations and companies co-create digital health solutions with the economic support of public regional funds. inDemand applies at the same time demand-driven and co-creation approaches.

Part of interest: The entire tool.

Target groups: Providers, Professionals, Patients, RPOs, Innovation business

→ **Link to the document**

139. Guide on public engagement and co-creation

The Guide (drafted in the framework of TeRRIFICA project, Deliverable D4.1., 2019) describes tools, activities, and methodology for stakeholder engagement and co-creation for climate change, on the basis of pilot projects carried out by TeRRIFICA. In particular, the focus is on how addressing possible conflicts and challenges on public engagement. The document might be useful for stakeholder mapping and engagement (section A) and for co-creation activities (section C). Each part contains examples based on TeRRIFICA experiences.

Part of interest: Pp. 28-35 for co-creation; Pp. 36-50 methods of engagement and co-creation. Challenges to engagement and co-creation Pp. 51-73.

Target groups: Policymakers, CSO, RPOs, Innovation business

→ **Link to the document**

140. InDemand Co-creation and Business Support Handbook

This is the Handbook on co-creation and business support services drafted and used during the third phase of the InDemand Project on co-creation and business support management. The Handbook describes the support activities that are being deployed during the co-creation phase by a mentorship and coaching program. It describes also the activities for the development of the solution by a co-creation health lab and a business modelling support (definition of the business model; go-to-market strategy; funding).

Part of interest: The entire document.

Target groups: Innovation business, RPOs, Policymakers, Patients, CSOs, Providers, Professionals

→ **Link to the document**

141. Co-design for health & Care. Manifesto of Co-design for health & care

This is a Manifesto (in Italian and English) set up by Open dot in collaboration with TOG Fondazione Together to Go, on co-design on health and care. The Manifesto contains 8 principles to follow in co-design activities to create new solutions by generating innovation. The Manifesto allows to adapt, personalise, and even create more effective solutions from scratch, taking into account the fact that people have not unique tastes and necessities. Citizens have not to be seen just as patients of a certain pathology. The principles are: listen and observe, speak the same language, share the needs, think and design together, prototype, share, and replicate and communicate. The Manifesto is linked with a toolkit.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, CSOs, Providers, Patients, Professionals

→ **Link to the document**

142. SISCODE Co-design for society in innovation and science – Co-creation in RRI practices and STI policies

This is the Deliverable D1.2 of the SISCODE project. The document contains reviews of literature respectively dedicated to: a comparative analysis of co-creation in policy-making at large, and in STI policy making in particular; a comparative analysis of co-creation methodologies and tools that can be applied in RRI practices.

Part of interest: In particular the chapter 4 on design for policymaking, chapter 5 on the co-creation in RRI practices, and annex 1.

Target groups: Policymakers, Payers, RPOs, Innovative Business, Providers, Patients, CSOs

→ **Link to the document**

143. SISCODE Toolbox for co-creation journey. Co-creation for society in innovation and science

The SISCODE Toolbox (2019) aims to facilitate the design and implementation of co-creation journeys for the SISCODE laboratories, focussing on better understanding and prioritisation of the particularities of each context. The toolbox contains a selection of existing tools for the development of the design-based co-creation process from the context analysis, to reframe the problem, to envision and ideation of a solution, the development of a prototype and its experimentation in a real-world context.

Part of interest: The entire document and in particular the part on Envision and Ideation of the solution.

Target groups: RPOs, CSOs, Innovation Business, Policymakers

→ **Link to the document**

144. Cimulact Inspiration catalogue for consulting different groups

This catalogue, set up in the framework of Cimulact Project (available online and in pdf format – 2018), contains a description of methods for involving different groups of stakeholders and citizens in participatory research agenda-setting. Those methods are: citizens' vision workshop; vision clustering workshop (extract commonalities or underlined needs from visions); research agenda camp (co-creation workshop): from commonalities or needs to research programme scenarios; who, what & why method; consensus workshop; enrich by co-design; prototyping research programme scenarios; the caravan; group interview with a co-design session; facilitated stakeholder working group; word cafe. The catalogue contains also a glossary, a table on the usefulness of citizen/stakeholder participation and guidelines on recruitment, and info on logistics. The catalogue is useful also for co-creation and prototyping activities.

Part of interest: All the resources, and in particular those for co-creation and prototyping.

Target groups: CSOs, Policymakers, RPOs, Innovation business, Payers, Providers

→ **Link to the document**

145. Digital Health Europe – Catalogue

Digital Health Europe will provide comprehensive, integrated, and centralised support to the Digital Health and Care Innovation initiative in the context of the Digital Single Market Strategy. The project's approach involves a number of actions that will boost innovation and advance the Digital Single Market priorities for the digital transformation of health and care (DTHC). The catalogue contains practices of digital solutions in healthcare, including those related to the management of healthcare for Covid-19 pandemic. This resource might provide useful information about innovation policies and good practices.

Part of interest: The entire catalogue.

Target groups: Policymakers, Providers, Professional, Patients, CSOs, RPOs, Innovative business, intermediaries, Payers

→ **Link to the document**

146. Innovation in Health: A guide to transforming healthcare through collaboration

This guide of Nesta Foundation (2017) explores the ways that companies, governments and researchers around the world are collaborating to improve the innovation process in health, from the way that problems are identified to how new products and services are created and then adopted by providers of healthcare. The guide describes three steps of innovation: problem identification; invention; adoption and diffusion; cross-cycle initiatives. Aims of this innovation guide are: making health innovation more efficient; informing health innovation with a better understanding of the health

system and patient/citizen needs; making health innovation more democratic. In all the innovation phases it is foreseen the involvement of citizens and professionals.

Part of interest: The entire document and in particular from Pg. 10 to 65.

Target groups: Policymaker, RPOs, Innovation business, CSOs, Providers, Professionals

→ **Link to the document**

147. Go Nano co-creation toolkit

The EU-funded GoNano Project enables co-creation between citizens, civil society organisations, industry, researchers, and policymakers across Europe to align future nanotechnologies with societal needs and concerns. GoNano co-creates with different stakeholder novel suggestions for future nanotechnology products. On the portal, there are: a knowledge database, several co-creation tools developed by profit and non-profit organisations, and examples of co-creation initiatives with citizens and stakeholders on nanotechnology in health.

Part of interest: See all the co-creation tools.

Target groups: Policymakers, Providers, Professionals, RPOs, Innovation Business, CSOs

→ **Link to the document**

148. eHealth Hub Solution Match Report

This is a resource tied with the eHealth EU Funded Initiative. In February 2017, Hospital Bernal, a private hospital located in the Region of Murcia (Spain), asked eHealth HUB to help them to identify and evaluate digital solutions to remotely monitor low-complexity chronic patients from their homes. Hospital Bernal was particularly interested in monitoring at least Chronic Obstructive Pulmonary Disease (COPD), Congestive Heart Failure (CHF), and Diabetes. eHealth HUB's first Solution Match was launched and a European-wide public call for solutions was opened. This Solution Match report features and compares the solutions of 71 responses to this call. The document accompanies the call for proposals.

Part of interest: The entire document.

Target groups: Innovation Business, RPOs, Providers, Professionals, Patients, Payers

→ **Link to the document**

149. Hacking health: bottom-up innovation for healthcare

This is an article (by Chowdhury, 2012) on Hacking Health experience held in Canada in 2012. The hackathon was focused on social innovation (with at least an education aim) more than technical innovation. The approach is aimed to improve healthcare to pair technological innovators with healthcare experts to build realistic, human-centric solutions to front-line healthcare problems. The hackathons may be focused directly on launching apps. From the onset, Hacking Health was

designed to catalyse entrepreneurial teams and projects to address issues in healthcare through business models.

Part of interest: The entire article.

Target groups: Innovative Business, Start-ups, RPOs, Professionals

→ **Link to the document**

150. Health Hackathons drive affordable medical technology innovation through community engagement

This is a chapter of Technologies for Development (by Mantzavinou et al., 2018) describing the experiences of MIT Hacking Medicine, a group founded in 2011 at MIT, aims to energize the healthcare community and accelerate medical innovation by carrying out co-creation through health hackathons. These 1- to 3-day events bring together diverse stakeholders to solve pressing healthcare needs. The hackatons aim to generate a network of individuals compelled to make healthcare better by exchanging ideas, knowledge, and skills in the long term. The article describes the activities needed to prepare and implement an hackaton.

Part of interest: The entire article.

Target groups: Providers, Professionals, RPOs, Innovation Business, CSOs

→ **Link to the document**

151. NESTORE – Your pathway to wellbeing

NESTORE is an innovative personalised ICT coaching system to support healthy ageing, based on co-design principles. The NESTORE system aims at putting the user at the core of the design process in order to address one of the biggest challenges of our century: "how to develop technologies that are useful and usable for the target users?". This system has been defined by a co-design process used for informing technologists on the user's needs and desires. The need collection of users is described in the deliverable "D7.1. Needs, values and suggestions to Co-design"; the further co-design for improvements the prototype is described in deliverable D7.3 Report on end-user improvement for prototypes, related to the validation initiatives with stakeholders carried out in 3 EU countries. The website contains also use cases and illustrations of the technology.

Part of interest: See Deliverables D7.1 and D7.3.

Target groups: Policymakers, Providers, RPOs, Business Innovation, High Education Institutions

→ **Link to the document**

152. The social labs Field Book. A practical guide to next–generation social labs

This is a practical guide on social labs (by Hassan, 2015). The Field Book describes what is a social lab, how to implement it, considering its three characteristics: as a laboratory, a space for multi-disciplinary collaboration and a strategy for addressing a complex challenge. In particular, the Field Book attempts to support practitioners who are interested in building social labs. It provides practical, step-by-step guidance as to how to design spaces, run processes and build the team requires to run labs. The approach suggested is to work consciously on the design of each stack and cultivate each of these stacks over time.

Part of interest: The entire document.

Target groups: Innovation business, RPOs, Policymakers, Patients, CSOs, Providers, Professionals, Intermediaries, Higher education institutions

→ **Link to the document**

153. Toolkit for organising healthcare prototyping sessions

The aim of this resource (set up in the framework of CAREABLE project) is to share knowledge about organising co-creation sessions for making healthcare solutions and enabling others to organise such sessions in which the innovative capacities of different people can lead to meaningful healthcare innovation. This resource should be used as a guidebook. It might be used to decide on a setup for tools, but also for templates for exercises help people in developing the healthcare solution that they feel is needed.

Part of interest: Pp. 2-28.

Target groups: Providers, Professionals, Patients, CSOs, Business innovation

→ **Link to the document**

C.5. Legal, ethical and privacy requirements in co-creation research and innovation

In CHERRIES, ethical, legal, and social requirements have to be incorporated in an open and responsible way in the co-creation process from the start. Furthermore, the challenge here is to promote the incorporation of these requirements in the innovation business model of the organizations involved in the three regional pilots in Örebro (Sweden); Murcia (Spain), and Cyprus.

This subcategory, therefore, contains resources on ethical (including privacy issues), societal and legal requirements that have to be incorporated from the beginning in co-creation activities, and above all in the healthcare field (ethics by design/privacy by design). These requirements are particularly relevant for those innovations based on ICTs, on big data and data management, smart technologies, AI, robotics, genomics, or human enhancing technologies.

In this regards many issues are being debated, such as: the use of human embryonic stem cells; the research on animals; the privacy protection and the protection of personal identity; the collection, control, and management of health data and informed consent; the application of the precautionary principle; the definition of legal responsibility, the management of uncertainty of the possible ethical and social impact of new technologies, etc.

The resources collected in this subcategory deal with these and other issues. Most of them are produced by EU projects, several are specifically addressed to SMEs for dealing with ethical issues, providing tools, grids, self-reflecting tools (inspired by the Canvas model) aimed at incorporating ethical issues in the innovation business.

154. Responsible Innovation in practice: experiences from industry

The PRISMA Project involved social science researchers and technologists from five different research organisations around the EU talking to eight technology projects about Responsible Research and Innovation (RRI). The goal was to draw specific lessons about how RRI can be implemented in practice in the industry. The document presents two different approaches in embedding RRI: an approach focused on external support to the industry; and an approach based on the embedding of ethicists in the research team. The document contains in its normative part, some legal and ethical aspects that have to be taken into consideration in the ICT co-creation and innovation activities, such as privacy protection and use of personal data; data ownership; transparency and open access; democratic consent; distribution of risk and harm; and sustainability.

Part of interest: the part on the social and ethical aspects related to innovation (Pp. 9-15).

Target groups: RPOs, Innovation Business

→ **Link to the document**

155. Legal and ethical inventory and in-depth analysis

This document, drafted in the framework of CAREABLE Project (Deliverable D6.1.), is focusing on privacy and data protection, intellectual property legal framework, liability, and medical devices, and ethics to be taken into account in the innovation process in health. Careables.org online platform represents a central hub for sharing knowledge for reproduction and self-creation of customised healthcare solutions, where individuals with particular needs, healthcare professionals, makers, designers, donors, and co-founders work collaboratively online in order to create custom-made healthcare solutions. The resource contains an inventory of ethical and legal rules that have to be considered in healthcare innovation and creation.

Part of interest: The entire document.

Target groups: Patients and CSOs, Policy Makers, Providers, Professionals, Innovation business, Payers, RPO

→ **Link to the document**

156. Ethics assessment for research and innovation – Part 2 Ethical impact assessment framework

This is the framework on ethical impact assessment defined by SATORI Project and approved by the European Committee for Standardisation by a CEN Workshop agreement CWA17145-2. The framework is focused on innovation and it has been developed on the basis of an analysis of existing research practices and their results. It consists of two parts. Part 1 makes recommendations for the composition, role, functioning, and procedures of ethics committees. Part 2 provides researchers and organisations with guidance on an ethical impact assessment; a comprehensive approach for ethically assessing the actual and potential mid- and long-term impacts of research and innovation on

society. The document contains also terms and definitions; a description of the phases of ethical assessment and of the possible tools to be used.

Part of interest: See in particular part 2.

Target groups: Innovation Business, RPOs

→ **Link to the document**

157. Ethics Canvas Manual

This Manual has been drafted by the ADAPT Centre & Trinity College Dublin and the Dublin City University (by Lewis, Reijers, Pandit) in 2017. The Manual allows researchers to reflect on the ethical impacts of their works by using the provided forms and templates. In particular, it might help to brainstorm about the ethical implications of a project and representing them in a Canvas; to analyse the ethical concerns of a project and find a similar solution. It contains also the proposal to join the Ethics Canvas community. There is also an online version of the Ethics Canvas Manual.

Part of interest: The entire document.

Target groups: Innovation business, RPOs

→ **Link to the document**

158. Guidelines for management and processes development for Responsible research and innovation – UNI/PdR 27:2017

This UNI/PdR sets out all useful criteria so that the organisations may carry out the innovation process in a responsible manner, i.e., aimed at the improvement of the quality of life, according to the interested parties' expectations, and at the same time be environmentally, socially and economically sustainable. The approach is based on the following principles: description of the phases; risk management; applying the precautionary principle; identifying, reviewing, and managing the indicators; identifying the objectives; reviewing the performance of indicators; the relationships with all the actors involved in the innovation value chain; dissemination.

Part of interest: The entire document. It contains also the templates and questionnaires to be used for applying it.

Target groups: Innovation business, RPOs

→ **Link to the document**

159. Guidelines to frequent legal and regulatory challenges of European eHealth SMEs

The guidelines describe the most frequent legal and regulatory challenges of European SMEs, with particular regard, among others, to privacy protection and GDPR requirements and IPR. This is one of the smart guides provided by eHealth Hub.

Part of interest: The entire document.

Target groups: Innovation Business, RPOs, Start-ups

→ **Link to the document**

160. The InFieri Assessment Tool for Responsible Innovation in Health

InFieri is a research program that focuses on Responsible Innovation in Health (RIH) carried out by the University of Montreal in Canada (Quebec, Ontario) and in Brazil (state of São Paulo). The RIH Assessment Tool was developed and validated by InFieri to assess responsibility in health innovation. In particular, it might be used by policymakers and providers to assess whether an innovation qualifies as a Responsible Innovation in Health (RIH). A User Guide has been developed to facilitate the application of the Tool. Drawing on RRI and health policy research, the RIH Tool entails a three-step process: screening, assessment, and rating. The value domains and attributes used for the assessment of innovation includes among others, also, ethical, legal, and social issues; health inequalities; frugality; eco-responsibility; inclusiveness.

Part of interest: The entire tool.

Target groups: Policymakers, Providers, Innovation business, RPOs

→ **Link to the document**

161. Responsible Innovation Lab Report and Roadmaps-Biomedicine

The document presents how the thematic Lab on biomedicine was run in Spain for the biomedicine sector, in the framework of Innovation Compass Project (Deliverable D2.4). The Lab consisted in a series of online and in-person meetings to develop a sectorial roadmap to help SMEs in the health sector to embed RRI in their practices. An important central issue of the Lab on Biomedicine is the ethical imperative of care and to recognise the need to afford greater choice for people in managing their health (and their access to technologies that help them do this). Such issues are noted as impacting on the designs of products (e.g., 'safe by design') and service configurations whereby users (patients) are empowered. It follows then, that the roadmap requires companies to have and implement appropriate codes of practice that help to embed an appropriate service ethos – and that related technologies are designed to support this.

Part of interest: In particular, the Roadmap.

Target groups: Innovation Business

→ **Link to the document**

162. My health, My data – Study Report

The Project My Health My data (this resource is the Deliverable D7.4) is focused on a new paradigm in Data privacy e data security in Health and in particular on Blockchain technology for innovation in (digital) health and privacy, preserving big data technologies in health. Issues of data subjects' privacy and data security represent a crucial challenge in the biomedical sector more than in other industries. The current IT landscape in this field shows a myriad of isolated, locally hosted patient data repositories. MyHealthMyData (MHMD) aims at changing the existing scenario by introducing a distributed, peer-to-peer architecture, based on Blockchain and Personal Data Accounts. The document presents the results of a consultation of users/citizens about their needs and expectations on the new approach on health data by citizens. This resource might provide suggestions to be taken into account in setting up, implementing innovation and tools requiring the collection and management of citizen health data

Part of interest: The entire document.

Target groups: Providers, Professionals, Patients and CSOs, Innovation business, RPOs

→ **Link to the document**

D. ADOPTION, IMPLEMENTATION, AND DEPLOYMENT OF INNOVATION SOLUTIONS

This category is focused on the processes of adoption, implementation, and deployment of the solutions identified with a participatory approach described in category C. It is focused also on the embedment of the CHERRIES demand-driven innovation approach in the innovation processes and RRI in organisations and industries. As the resources collected here show, a solution, can be of different kinds: a product (including also ICT app or software), a service, or a social innovation (new ideas addressing more effectively unmet needs, creating social relationships, and forming new collaborations, change in the business model or in the innovation process). Due to this diversity, also the adoption and implementation practices of the solution can take different forms, also in relation to the kind of actors involved in its co-construction. The resources describe some of these practices.

Adoption and implementation in the case of a product implies its access to the market and its commercialisation requires its pollicisation and knowledge among potential users (citizens, patients, professionals, providers, etc.). Commercialisation and access to the market of prototyped and tested products are crucial points for many start-ups and industries, and they require measures to support demand and market creation in order to help innovations to overcome the "valley of death". Two subcategories are specifically focused on commercialisation and innovation in Pre-Commercial Procurement and Public Procurement of solutions. Pre-Commercial Procurement represents a possible interesting way to access the market.

For industries and SMEs, adoption and implementation mean also the incorporation of the RRI approach (6 keys and/or 4 dimensions) and/or of CHERRIES demand-driven approach in the process of production of the solution/product, such as the involvement of users and stakeholders, the integration of ethical and social aspects by design, etc. In this framework, one of the subcategories is focused on the description of implementing practices of RRI or of RIH (Responsible Innovation in Health) approaches in healthcare (on which a focus is also devoted in Part One of the Toolbox). It is important to note, that embedding RRI might concern also the culture, the norms, the rules, and the same identity of an organization, requiring for this, the implementation of an institutional change process. In the case of social innovation (i.e., products, services, models, practices, etc.) adoption and implementation means up-scaling, its transferability to other contexts, and its sustainability, with a definition and management of the relative requirements and conditions.

In CHERRIS Project, the adoption and implementation of the solutions co-created in the three pilots in Örebro (Sweden); Murcia (Spain), and Cyprus will be supported by different kinds of activities, such as business intelligence in market creation within a given territory;

dissemination and exploitation; the organisation of impact investment workshops (including training and a pitching session) involving sectorial investors interested in the solutions among the organisations involved in the pilots and the CHERRIES community and beyond. Furthermore, some materials produced or being produced in the framework of CHERRIES Project might be very relevant to the adoption and implementation of the solution.

The resources of this category are divided into the following subcategories:

D.1. Solution implementation
D.2. RRI and Responsible Innovation in practice
D.3. Pre-Commercial Procurement: a possible way for innovation to market access
D.4. Commercialisation

D.1. Solution implementation

The resources of this subcategory describe different forms of adoption and implementation deployed in various contexts, varying on the basis of the type of co-created solutions involved (a product, a service, a model, a social innovation, etc.) able to address specific needs or challenges.

This section contains also resources about the scaling-up process of innovation. Other resources describe different practices and experiences for the adoption of the RRI approach (and in particular of its six keys), including an inventory of possible implementing practices on gender equality, open access, science education, and public engagement; a portal on open science and innovation (with access to a glossary, resources, and experiences); an account about a long-term experience in adopting RRI criteria in a funding research organization. Two resources describe the process of integration of RRI approach (keys and dimensions) within the regional innovation policies, as criteria for funding initiatives.

Some resources are also focused on social innovation, containing useful and inspiring reflections on its different phases of implementation, according to the type of involved organizations (social movements, market organizations, policymakers, academia, etc.). Implementing social innovation will allow to address unmet needs, in a more effective way, pursuing the benefits of all the community, by overcoming boundaries between disciplines, approaches, etc. The up-scaling process of social innovation is also described and explained (with advices and suggestions) in one of the resources.

The subcategory includes also two experiences describing the adoption of co-created solutions in healthcare. The first one (related to the InDemand project) reports the experience of healthcare systems in adopting solutions co-created by applying a demand-driven innovation approach. The second one documents the experience of Activage Project, aimed at setting up an interoperable IoT ecosystem for promoting an active and healthy life for aging people built on the basis of user experiences.

What follows are resources for the "solution implementation".

163. Rri practices in healthcare

The second episode of the "CHERRIES webinar series 2020 Exploring responsible healthcare ecosystems in Europe" was devoted to a reflection on "RRI practices in healthcare", with the contribution of two experts: Rosina Malagrida, Head of the Living Lab for Health at IrsiCaixa & Co-coordinator of the Barcelona "la Caixa" Living Lab, and Barbara Kieslinger, Coordinator of Careables.org and Project Manager at the Centre for Social Innovation – ZSI, Vienna.

Part of interest: The entire webinar.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

164. Digital Health Europe – Catalogue

Digital Health Europe provides comprehensive, integrated, and centralised support to the Digital Health and Care Innovation initiative in the context of the Digital Single Market Strategy. The project's approach involves a number of actions that will boost innovation and advance the Digital Single Market priorities for the digital transformation of health and care (DTHC). The Platform contains practices of a digital solution in healthcare, including those related to the management of healthcare for Covid-19 pandemic.

Part of interest: The entire catalogue.

Target groups: Policymakers, Providers, Professional, Patients, CSOs, RPOs, Innovative business, intermediaries, Payers

→ **Link to the document**

165. Ubora Platform

UBORA is a platform for open-source co-design of new solutions to face the current and future global healthcare challenges, by exploiting networking, knowledge on rapid prototyping of new ideas, and sharing of safety criteria and performance data. UBORA ("excellence" in Swahili) brings together European and African Universities and their associated technological hubs (supporting biomedical prototyping laboratories and incubators), national and international policymakers, and committed and credible stakeholders propelled by a series of Design Schools and Competitions.

Part of interest: The entire platform.

Target groups: RPOs, Innovation business, Providers, Patients, CSOs, Higher Education Institutions

→ **Link to the document**

166. Patient Innovation Platform

It is an online Platform where patients and caregivers around the world share the solutions they have developed also with the help of collaborators (other caregivers, professionals, etc) to cope with a health-related problem. The platform contains more than 150 solutions provided by people coming from more than 80 countries. The portal contains also a section devoted to COVID 19, including solutions concerning mobile apps, protective equipment, lung ventilator, websites, electronic devices, etc.

Part of interest: The entire platform.

Target groups: Innovation business, CSOs, Patients, Providers, Professionals, RPOs

→ **Link to the document**

167. Guidelines for the adoption of Activage solution in other Pilots

ACTIVAGE is a European Multi Centric Large-Scale Pilot on Smart Living Environments. The main objective is to build the first European IoT ecosystem across 9 Deployment Sites (DS) in seven European countries, reusing, scaling up, and integrating underlying open and proprietary IoT platforms, technologies, and standards. The specific aim is to provide interoperability across these heterogeneous platforms, enabling the deployment and operation at the large scale of Active & Healthy Ageing IoT based solutions and services, supporting and extending the independent living of older adults in their living environments, and responding to real needs of caregivers, service providers, and public authorities. The guidelines address the need at this moment of the deployment of the ACTIVAGE pilots of collecting and documenting a series of experiences that can be translated into a series of recommendations for the replication of the same in another series of projects.

Part of interest: See in particular, paragraphs 4.1., 4.2., 5.3., and chapter 6.

Target groups: RPOs, Innovation business, Providers, Patients, CSOs, Policymakers

→ **Link to the document**

168. InDemand Stories

The resource contains stories of the application of the InDemand Project model in the three regions of Murcia (Spain), Paris (France) and Oulu (Finland): describing the challenges and the solutions implemented. Each region has identified specific challenges to be addressed by the solution proposed by the applicants. The resource describes for each story the challenges identified, the co-created solutions, and the participants that made it possible. The solutions are being implemented by healthcare providers and institutions.

Part of interest: The entire document. In particular, see Gravidity; A3D and Arno and Anonymous.

Target groups: Innovation Business, RPOs, Providers, Professionals, Patients, Payers

→ **Link to the document**

169. Marie Interreg project – Mainstreaming Responsibility into innovation policy

MARIE is an Interreg project involving 8 EU regions. Its objective is to improve regional public policy that supports the delivery of RRI to enterprises' product, process, and service design, production, and distribution and promote the integration of RRI approach (key and dimensions) in organisations. MARIE achieves this aim through exchanging experiences on 3 types of support action contained in the RRI framework: Quadruple Helix; Open Innovation; Information & Tools for RRI application. Using interregional activities, communication, and stakeholder engagement, partners develop Action Plans that result in: improved policy instruments; more and better-targeted funding for RRI delivery; increased capacity among innovation actors; consolidated partnerships of quadruple helix innovation chain stakeholders. The resource describes the implemented practices, and the impacts already produced in the 8 regions.

Part of interest: The entire resource.

Target groups: Innovation Business, Policymakers, CSOs, RPOs, Start-ups, Intermediary organisations

→ **Link to the document**

170. Interreg – ROSIE Project

The main objective of the ROSIE Project was to use transnational cooperation to improve skills among entrepreneurs and innovation actors to promote RRI in Small and Medium Enterprises (SMEs) in Central Europe. Results of the project are tools and training modules to improve RRI capacity, with a comprehensive RRI strategy and transnational pilots to test tools and strategic proposals. The main outputs of the ROSIE project are the road maps and national pilots. The resource describes the approach and methods followed in the pilots for embedding RRI: UNI/PdR, STIR, Living Lab, used COMPASS RRI self-Check tool.

Part of interest: See in particular the part devoted to approach and methods.

Target groups: Innovation Business, RPOs, Policymakers, Intermediaries, Start-ups, Intermediary organisations

→ **Link to the document**

171. C(i*EMP) strategy

The document (Region de Murcia, 2017) describes the strategy to foster innovative entrepreneurship based on the STEM vocation for the period 2017-2021. The strategy for the period 2017-2021 presents some changes with respect to the precedent strategy: coordination and communication; community and society; cooperation and labour; learning; enterprises; innovation, science, technology, and development; empowerment; entrepreneurship.

Part of interest: The whole document.

Target groups: Innovation business, RPOs, Policy makers

→ **Link to the document**

172. Inventory of RRI governance innovation practices

This document (TeRRItoria Project, Deliverable D3.2, 2019) is an Inventory of 43 RRI Governance Innovation Practices, detected in 15 RRI projects conducted in Europe and beyond, proposing relevant and new models of RRI governance innovation practices. Based on the analysis of the 15 RRI projects, the report underlies the reflexive and the context-depended nature of RRI, requiring for its integration a tailored approach that needs to take into account the existing problems, the aspired future situations, as well as the agency and the capacities of the actors (individuals, or organisations). The summary contains a list of possible practices and approaches that might be inspiring in applying RRI (gender equality, public engagement, science education, and open access) and a list of practices adopting a unified approach on RRI.

Part of interest: The entire document, and in particular the summary.

Target groups: Policymakers, Providers, Professional, Patients and CSOs, RPOs, Innovative business, intermediaries

→ **Link to the document**

173. Foster Portal

The Foster Portal is an online collection of training materials on RRI and Open Science. In particular, it contains: an integrated RRI and OS taxonomy and a knowledge repository showing resources linked to RRI in different subcategories (videos, tutorials, and guidelines).

Part of interest: The entire portal.

Target groups: RPOs, Innovation Business. Higher Education Institution

→ **Link to the document**

174. Scaling Innovative care for Rare disease & complex conditions

INNOVCare aimed at researching integrated care pathways for rare disease patients, bridging gaps between social and healthcare, and facilitating the organisation of everyday life for them and their families. The report (Deliverable D9.5, 2018) presents the theoretical and methodological framework of the up-scaling process and the way for adopting and implementing social innovation in other contexts. Up-scaling describes the effort to increase the impact of (social) innovations.

Part of interest: In particular, see from Pg. 8 to 12 and from Pg. 36 to 58.

Target groups: Policymakers, Patients, Providers, RPOs

→ **Link to the document**

175. Social innovation: What it is, why it matters and how it can be accelerated

The document (by Mulgan, and Sanders, 2007) addressed the issue of social innovation: what it is (new ideas that meet unmet needs); who do it (politics and government, markets, movements, academia, and social enterprises); how the stages of social innovation happen; linear and not linear process of social innovation; the innovation stages performed by different actors; the future of social innovation. Social innovation happens in different fields and is promoted by different kinds of actors (not only the non-profit sector). The theoretical discourse is accompanied by a description of stories and experiences.

Part of interest: The summary (Pp. 4-7) and the stages of social innovation (Pp. 21-34).

Target groups: Policymakers, RPOs, Innovation Business, CSOs

→ **Link to the document**

176. Advances and Challenges in Innovation Studies

The paper is focused on innovation, considering four main strands of research, studying innovation at the organisational, systemic, sectoral, and macroeconomic levels. Several fundamental issues are explored, such as the co-evolution between technological and institutional change; the role of demand; and the impacts of innovation on individual and collective welfare. There are also important methodological challenges, such as the need for more systematic interactions between the different levels of analysis; the importance of an interdisciplinary approach to the study of technological and institutional changes; and the search for a combination of contingent explanations based on case studies with general analytical results based on econometric and formal models. The article describes also the regional network of innovation actors.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business

→ **Link to the document**

D.2. RRI and Responsible Innovation in practices

The processes of adoption and implementation concern also the integration of RRI approaches in health innovation and related business models. In particular, this subcategory is focused on two specific areas: the area of healthcare systems, also taking into consideration the approach of RIH – Responsible Innovation in Health and the area of SMEs and Industries, in which RRI adoption seems more difficult and less developed in comparison with the area of Academia/research organisations. In both these areas, the attention is mainly focused on the adoption and integration of the four dimensions of RRI (anticipation, inclusion, reflexivity, responsiveness). Especially in the case of SMEs, the four dimensions seem to be more compatible with the experiences of industries (also with respect to other approaches on responsibility such as CSR).

Some of the resources describe in detail the RIH approach and how to use it and its tools for assessing responsible innovativeness in the health sector of products and production processes (see also Section E). Two other resources illustrate the RRI Award in health and an application of the four dimensions RRI in the eHealth experiences. For many years the ICTs have been one of the domains characterized by an effort to introduce the RRI approach.

Various resources, produced in the framework of European projects, such as Responsible Industry and PRISMA, provide methods and guidance and describe concrete experiences of integration of RRI dimensions in the business model and production processes of industries and SMEs. All these resources provide in different ways, inspiring and useful guidance and tools on how the principle of responsibility in innovation processes and business should be deployed.

The identified resources follow.

177. Introducing responsible innovation in health: a policy-oriented framework

This is a paper (by Silva, Lehoux, Miller, and Denis, 2018) inspiring the experience of InFieri. It describes the components of the RIH framework, based on the literature on RRI and health innovations. In particular, the framework integrated the RRI characteristics of addressing societal needs and challenges; engaging a range of stakeholders to improve decision-making and mutual learning; anticipating potential problems, assessing available alternatives and reflecting on underlying values, assumptions and beliefs; and providing guidance on ways to act following the previous principles; with the three other criteria of innovativeness, health relevance and subsidiarity. Using these criteria, the authors set up an inventory of around 100 innovations in health matching RIH criteria.

Part of interest: The entire document.

Target groups: Innovation Business, Policymakers, CSOs

→ **Link to the document**

178. The InFieri Assessment Tool for Responsible Innovation in Health

InFieri is a research program that focuses on Responsible Innovation in Health (RIH) carried out by the University of Montreal in Canada (Quebec, Ontario) and in Brazil (state of São Paulo). The RIH Assessment Tool was developed and validated by InFieri to assess responsibility in health innovation. In particular, it might be used by policymakers and providers to assess whether an innovation is qualified as a Responsible Innovation in Health (RIH). Drawing on RRI and health policy research, the RIH Tool entails a three-step process: screening, assessment, and rating. The RIH assessment Tool includes four inclusion and exclusion criteria, nine assessment attributes, and a scoring system. The resource contains the User Guide developed to facilitate the application of the Tool.

Part of interest: The entire tool.

Target groups: Policymakers, Providers, Innovation business, RPOs

→ **Link to the document**

179. Responsible Research and Innovation: a productive model for the future medical innovation

This is an article (by Demers-Payette, Lehoux, and Daudelin, 2016) presenting the outcomes of three mixed focus groups, involving users of medical technology (patients, clinicians), developers (engineers, designers), and innovation managers (of universities, in hospitals, and in biomedical firms) about the issues RRI and innovation in health. It is aimed at identifying needs and challenges in the healthcare system, by a discussion on the four RRI dimensions (inclusion, anticipation, reflexivity, responsiveness). The resource provides useful suggestions for the further development of responsible medical innovation.

Part of interest: The entire article.

Target groups: Innovation Business, RPOs, Patients and CSOs, Providers, Professionals, Payers

→ **Link to the document**

180. Synthesizing an implementation framework for responsible research and innovation

This article (by Fraaije and Flipse, 2019) proposes an implementation framework of responsible research and organisation in SMEs, based on the operationalisation of the RRI dimensions − i.e., inclusion, anticipation, reflexivity, and responsiveness. The framework, mainly addressed to engineers and practitioners, is based on a literature review. The resulting framework integrates a set of qualifiers that are central to the concept of 'responsive' research and innovation, from the point of view of the process of innovation and the point of view of the product. These are the qualifiers for the innovation process: transparency, inclusion, reflexivity, anticipation, responsiveness. The framework also allows the identification of 'RRI shortcuts' to be avoided.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business

→ **Link to the document**

181. Responsible Innovation in practice: experiences from industry

The PRISMA Project involved social science researchers and technologists from five different research organisations around the EU talking to eight technology industries about Responsible Research and Innovation (RRI). The goal was to draw specific lessons about how RRI can be implemented in practice in the industry. The document presents two different approaches in embedding RRI: an approach focused on external support to industry; and an approach based on the embedding of ethicists in the research team. The document describes the activities implemented by the Project in the 8 industries on how to embed RRI approach in their innovation programs.

Part of interest: From Pg. 19 to 50; from Pg. 57 to 63.

Target groups: RPOs, Innovation Business

→ **Link to the document**

182. Guide for the implementation of Responsible Research and Innovation in the industrial context

The Guide (drafted in the framework of Responsible industry Project) provides strategic options and recommendations to be considered on a case-by-case basis by industrial actors engaged in research and innovation to pursue responsible practices and behaviours when developing devices, products, and services. In particular, the Guide contains a Framework to implement RRI, developed on the basis of research undertaken by companies that are active in research and innovation in the domain of ICT. The Framework operationalises RRI in companies dealing with ICT for an ageing society addresses four main questions: Who is responsible for what? How can RRI be integrated along the value chain? What voluntary tools can be used for RRI? How can ethical and social impact analysis be performed?

Part of interest: The entire document and in particular the part of the Framework (Pp. 8-22).

Target groups: Innovation Business, RPOs

→ **Link to the document**

183. Company strategies for Responsible Research and Innovation (RRI): a conceptual model

This is an article (by Van de Poel et al., 2017) focused on how companies can integrate RRI (and mainly its 4 dimensions) into their Corporate Social Responsibility (CSR) policies and business strategy. The authors developed a conceptual model that links a company's RRI strategy to its context, and that helps to translate the RRI strategy into activities that result in RRI outcomes. A process for developing company-specific RRI key performance indicators (KPIs) that can support companies to measure RRI outcomes is also described. The framework distinguishes four main elements, namely context, strategic level, operational level, and RRI outcomes.

Part of interest: The entire document.

Target groups: Innovation business, RPOs

→ **Link to the document**

184. The role of user-led regional innovation networks in shaping responsible innovation in eHealth

This is an article tied with the CareConnect Project eHealth innovations in the Twente Region (by Konrad, Greiving, and Benneworth, 2018) and focused on the innovation process of an eHealth application, which emerged as a user-driven, local project. The eHealth application is based on a communication platform that creates a network around a particular patient, who needs regular care, including the different parties involved in the patient's care; and aimed at facilitating the communication and coordination of this care network. The authors trace the innovation and implementation process, and explore, firstly, to which extent and in which form different dimensions of

responsibility are presented along the innovation process. Secondly, they consider if and how the regional and partly local, bottom-up nature of the innovation network, was conducive to enacting the dimensions of responsibility. The article also describes the composition and function of the network.

Part of interest: The entire article.

Target groups: Providers, Professionals, RPOs, Policymakers, Innovation business, Patients, CSOs

→ **Link to the document**

185. Premios de investigacion e innovacion responsible RRI en salud (RRI Responsible Health Research and Innovation Awards)

The RRI Health Award is an initiative carried out in the framework of Project Orion, focused on promoting open science by the implementation of co-creation activities and training. The context included six modalities of participation (one for each RRI Key): ethics, governance, gender equality, open access, public engagement (here called "public commitment"), and health education, with a concept that seeks to encourage active participation and involvement of society in science and innovation from the earliest stages of research projects to ensure that future results are as aligned as possible with societal needs. Orion website contains also a menu of co-creation methods (Deliverable D3.1.).

Part of interest: The entire document.

Target groups: Policymakers, Providers, RPOs, CSO, Innovation Business, Higher Education Institutions, Payers

→ **Link to the document**

D.3. Pre-commercial procurement: a possible way for innovation to market access

The resources of this subcategory are focused on Pre-Commercial Procurement processes as a possible way for innovations to access to the market. The resources present also innovative practices in this field. As specified in the UE page on PCP, while Public procurement refers to the process by which public authorities, such as government departments or local authorities, purchase work, goods or services from companies, Pre-Commercial Procurement (PCP) refers to the mechanisms by which "public sector, from the demand side, challenges the industry to develop innovative solutions for public sector needs and it provides a first customer reference that enables companies to create competitive advantage on the market." As explained in the UE page on PCP, this form of procurement contains benefits for both the suppliers and the public procurers. "In PCP, public procurers share the benefits and risks related to the Intellectual Property Rights (IPR) resulting from the research and development (R&D) with suppliers at market price. Suppliers retain IPR ownership rights, while procurers keep some usage and licensing rights". Apart from the management of IPR issues, as stressed by UE (see the resources below), the use of PCPs provide shared benefits.

Nevertheless, PCP procedures are scarcely used. For this reason, the European Commission provides support for public procurers to use and implement PCPs. SMEs, big companies but also Research Performing Organisations, the Academia, and start-ups can participate in PCPs. As a matter of fact, CHERRIES project itself might be considered a PCP initiative. Even if due to its nature of R&D activities, PCP can go up to the development and the purchase of a limited volume of first products or services developed, it can represent a first step for accessing to the market and to commercialisation. The second step to commercialisation can be the use of the Public Procurement of Innovative Solutions (PPI) procedures.

In every case, PCP might represent a step forward the commercialisation of a product or a service and might help in overcoming the so-called "valley of death" of innovation. PCP/PPI implementation foresees the following phases: phase 0 curiosity-driven research; phase 1 solution design; phase 2 prototyping development; phase 3 original development and testing of a limited volume of 1st test product/service; PIPPI phase 4: deployment of commercial volumes of end-products; wide diffusion of the newly developed solution.

The resources collected here describe different innovative experiences of PCP in the healthcare sector, for different diseases and situations (e.g., home care, diabetes, digital health, aging, pain self-management, etc.) and by using a different way of implementation (platform, community of practices, etc.). In most of the resources, a crucial aspect of PCP is related to the involvement of users and stakeholders in collecting unmet needs. This aspect is also at the core of the experience of Oulu (Finland) where living labs have been used in Public procurement process. Two resources are focused on the need to innovate Public Procurement mechanisms. Some resources describe initiatives carried out at the level of a single hospital, while others describe experiences of large EU projects or initiatives, at different stages of PCP phases and the problems encountered.

What follows are the resources of this subcategory.

186. The role of public procurement in healthcare

The third episode of the "CHERRIES webinar series 2020 Exploring responsible healthcare ecosystems in Europe" was focused on "The role of procurement in healthcare innovation" with the contribution of John Rigby and Samuli Kauppinen, with a reflection on whether the innovation frameworks are changing towards more responsible and sustainable approaches and with a reflection on the question if the rules and the framework are ready enough to support this cultural change and to cope with the complexity of the health sector.

Part of interest: The entire webinar.

Target groups: Policymakers, RPOs, CSO, Innovation Business, Funding organisations, Intermediaries, Higher Education Institutions

→ **Link to the document**

187. PCP – Pre-commercial Public Procurement

The resource is the web page of the European Commission on Pre-Commercial Public Procurement. This is the UE definition: "PCP enables public procurers to compare alternative potential solution approaches and filter out the best possible solutions that the market can deliver to address the public need. Public procurers can drive innovation from the demand side by acting as technologically demanding customers that buy the development and testing of new solutions." Apart from IPR issues, PCPs produce benefits such as developing innovative solutions for the societal challenges of the future; facilitate the access of new innovative players to the public procurement market; share the risks and benefits of designing, prototyping, and testing new products and services between procurers and suppliers; improving the conditions for wider commercialisation and take-up of R&D results. PCP might be followed by the adoption of the Public Procurement of Innovative Solutions (PPI). "Public Procurement of Innovative solutions (PPI) happens when the public sector uses its purchasing power to act as early adopter of innovative solutions which are not yet available on large scale commercial basis".

Part of interest: The entire platform.

Target groups: Professionals, RPOs, Innovation Business, Patients, Policymakers, Start-ups, Intermediary organisations

→ **Link to the document**

188. PiPPi – Platform for Procurement of Innovation and Innovation of Procurement

PiPPi is an EU Project coordinated by The Center for Innovation at the Karolinska University Hospital to innovate procurement of digital health and care services, by establishing an active Community of Practice (CoP) of people, who wish to learn something by collaborating with other members of the group both in real and virtual world; and sharing goals, interests, information, and experiences. The

CoP is composed of policymakers, payers, enablers, industry, healthcare providers/hospitals, the research community, patients. The CoP has been involved in the process of identifying and formulating unmet needs in the digital healthcare and service area. This process was the basis for the activation of the PCP/PIPPI procedures. The works on unmet needs and their prioritisation is a loop process.

Part of interest: The entire platform.

Target groups: Professionals, RPOs, Innovation Business, Patients, Policymakers

→ **Link to the document**

189. ProEmpower

ProEmpower is a PCP project to buy R&D (research and development) services to improve the treatment and the self-management of diabetes type 2 patients using a Personalised Diabetes Management Solution. The solution has to be interoperable with respect to the existing systems of the pilot regions. The PCP includes the following steps: Open Market consultation (by webinars, focus groups); a call for tender; the implementation of phase I, by the definition of the concept design, the solution architecture and technical specification; the implementation of phase II, by the development of a prototype system in two iterations; the deployment of phase III, by the development and testing of a pilot system. The solutions have to apply the General Data Protection Regulation (GDPR) principles and the patients' data processing rights.

Part of interest: The entire itinerary.

Target groups: Innovation Business, Policy Makers, Start-ups, RPOs, Providers, Patients

→ **Link to the document**

190. Pre-Commercial Procurement methods for procuring R&D services

The RELIEF project – recovering life wellbeing through pain self-management techniques involving information and communication technologies (ICTs) – is a PCP project funded by the European Commission under the Horizon 2020 program. In this case, the challenge/need to be addressed by the solution requires more research. The challenge has been presented to industry/SMEs in an Open Market Consultation. A European call for tender of the solution has been launched. Then the PCP procedures started. The PCP of RELIEF includes the following phase: phase 1 solution design; phase 2 prototype development; phase 3 pre-commercial small scale productive/service development − field test ad comparison for selecting the 2 best solutions; phase 4 Commercialisation diffusion of product/service.

Part of interest: The entire documents.

Target groups: RPOs, Innovation business, start-ups

→ **Link to the document**

191. End-user Involvement Enhancing Innovativeness in Public Procurement. Evidence from a Healthcare Procurement

This paper (by Haukipure, Vainamo, and Torvinen, 2016) examines Public Procurement, aiming to increase understanding of how the living lab approach and end-user involvement create innovativeness and enhance public procurement results, providing effective and better solutions. The empirical findings are based on a real-life unique Public Procurement in the healthcare field where the living lab approach was used through the product testing phase, which was included in the procurement procedure. The selected group of users performed product testing in a real homecare environment. The quality of the product based on product testing played a significant role for the first time in public healthcare-related procurement in the City of Oulu, Finland. In this case, the winning solution was not the most inexpensive but the one obtaining the highest quality scores by users.

Part of interest: The entire article is useful because innovates the public procurement process with the introduction of living labs.

Target groups: Policymakers, RPOs, Innovation Business, Patients, Providers, Payers, CSOs

→ **Link to the document**

192. Procurement models for care services targeting aging population

This document was produced in the framework of the UNCAP Project (Deliverable D5.2., 2017). The deliverable describes relevant new public procurement models used in the public sectors that can be accommodated for future exploitation of the healthcare market by UNCAP. The document is based on the results of desk research and on the experiences carried out by the UNCAP project.

Part of interest: Download the Deliverable D5.2 and see the part devoted to the public procurement in each EU country and the conclusion.

Target groups: Innovation Business, Policy Makers, Start-ups, RPOs

→ **Link to the document**

193. Smartphone-based self-monitoring in bipolar disorder: evaluation of usability and feasibility of two systems

This is a paper (by Faurholt-Jepsen et al., 2019) related to the PCP EU project of NYMPHA-MD focused on support to people with bipolar disorders. During the PCP carried out in the framework NYMPHA-MD project, two Smartphone-based monitoring systems were developed by two IT companies, and their solutions were selected among other companies' innovative solutions during the PCP to be tested. The resource presents the multi-center pilot study carried out to examine the feasibility and usability of these systems (the Pulso system and the Trilogis-Monsenso system) for patients with bipolar disorder, developed and selected to be tested.

Part of interest: The entire document.

Target groups: Innovation Business, Policy Makers, Start-ups, RPOs, Providers, Professionals

→ **Link to the document**

D.4. Commercialisation of the solution

This fourth subcategory is focused on a crucial aspect of every innovation process, i.e., the access to the market and commercialisation of products and innovations, avoiding to waste time and resources to produce products and services that remain at the stage of a prototype. This is a big issue in particular for start-ups and SMEs. There is a big amount of studies and publications on this issue (including problems and obstacles in market access), as well as experiences, projects, and initiatives, to provide different forms of support at European, national, regional, and local levels (incubators, business angels, different forms of investment, public communication activities, accelerators, organization of events like labs, hackathons, awards, calls for funding, etc.).

As shown in the subcategory D3, Pre-Commercial Procurement initiatives might facilitate access to the market. Furthermore, as various resources collected in this toolbox suggest, a focus on the unmet needs of citizens, users, patients, professionals, and healthcare providers might facilitate the commercialisation. For this reason, the adoption of a bottom-up demand-driven approach by SMEs and industries is strongly recommended.

Thanks to the information and experiences collected implementing the three pilots in Örebro (Sweden); Murcia (Spain), and Cyprus, the CHERRIES Project is geared to identify policy recommendations on the use of RRI demand-driven approach for making innovation and business support in healthcare more apt to address societal needs.

All the resources collected here have a practical character so that entrepreneurs and innovators can find them useful for an assessment of their enterprise or their product. In particular, two resources contain practical guides on business, with particular regard to e-health products and solutions. Two resources, on the basis of experiences carried out in the framework of EU projects, include lists of obstacles and factors that might hinder access to the market. Three other resources are focused on the cycle of health tech innovation, on Technology readiness level and Market readiness level that might be used as reflecting tools in designing and implementing the commercialisation and sustainability processes.

Below the resources of this subcategory.

194. eHealth Hub Calls and events

In the framework of European E-Health Business Support, eHealth Hub is an EU-funded initiative, exclusively focused on digital health, providing long-term support to the stakeholder ecosystems and addressing key challenges of European SMEs: fine-tuning a business model, securing investments, engaging the demand-side, and accelerating commercialisation, getting legal and regulatory guidance to develop solutions in compliance with a multi-layer complex framework. eHealth Hub's goal is to provide business-oriented services tailored to the needs of eHealth SMEs and stakeholders and to secure their continuation after the project end via a sustainable support structure. The resource contains various smart guides.

Part of interest: The entire resource.

Target groups: Innovation business, Providers, RPOs, Start-ups, Intermediaries

→ **Link to the document**

195. eHealth Start-up Guide for business success

This is a practical introductory manual on business modelling and routes to market, drafted in the framework of GET project (2015). The Guide presents some approaches to business development in the sector of health. In particular, the Guide presents three approaches: business model Canvas, the lean start-up methodology, and the continuous improvement methods. Tools and resources are also included. Each approach is discussed individually to offer an outline structure and a fundamental level of understanding, together with links to tools, literature, and case studies for further details and references to help the application of these methods and to help the achievement of best success to eHealth start-ups.

Part of interest: The entire document.

Target groups: Innovation Business, Start-ups, Intermediaries, Payers

→ **Link to the document**

196. GET Funded – A practical guide for digital Health SMEs

On the basis of an analysis of a Single Digital Market (2015), the resource provides lessons learned from investors on the situation of digital health. In particular, the resource describes the investment framework in eHealth, with data and interviews with investors (GET project made interviews with more than 250 investors in digital health). The resource contains the list of criteria adopted to be taken into consideration by SMEs and start-ups in a self-assessment exercise on three areas of issues: when a company is ready for its next step; a product that is a solution; a company ready for its next round of investment. The resource contains also a list of potential investors in eHealth.

Part of interest: The entire document, and in particular from Pg 16.

Target groups: Innovation Business, Start-ups, Intermediaries, Payers

→ **Link to the document**

197. Adoption of digital health innovations: perspective from a stakeholder workshop

This is a paper (by Van Velthon and Cordon, 2017) describing the outcomes of a workshop on health stakeholders on driving factors, obstacles, and conflicts related to the adoption of digital health innovation.

Part of interest: The entire document.

Target groups: RPOs, Business Innovation, Providers, Professionals, CSOs, Patients

→ **Link to the document**

198. CIMIT Health care innovation technology

CIMIT (Consortia for improving medicine with the Innovation and technology) defined a set of instruments to support healthcare innovation technology development. The starting point is the healthcare tech innovation cycle (composed of three main phases: Invention, Translation, and Commercialisation), establishing a sequence of healthcare-specific milestones. In this context was created a roadmap to guide teams for navigating the complex journey from an unmet clinical need to the becoming standard of care; and able to address clinical, market/business, regulatory, and technology risks. The elements of the cycle are: clinical need; idea; proof of concept; proof of feasibility; proof of value; initial clinical trials; validation of solution; approval and launch; clinical use; standard of care. Several other instruments delivered from CIMIT are included in this resource.

Part of interest: The entire resource.

Target groups: Innovation business, RPOs, Start-ups

→ **Link to the document**

199. Guidance and Impact Tracking System (GAITS) platform

Guidance and Impact Tracking System (GAITS) platform is designed to assist the commercialisation of healthcare innovations. This is a free educational resource site to help teams who are developing healthcare innovations to plan their work in a way that maximizes the chances for success by using CIMIT's Healthcare Innovation Cycle framework. It is composed of a series of Deliverables grouped by maturity (10 "Innovation Maturity Levels") and topic areas (4 Domains), creating 40 Cells. Each Cell is divided into segments that represent a Deliverable. This tool was prepared for four types of solutions: health tech, med-tech, digital medicine, and biomarker diagnostic.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Providers, Start-ups

→ **Link to the document**

200. Technology readiness level and Market readiness level

The resource contains the tools of technology readiness level (TRL) and of the Market readiness level (MRL). The corresponding efforts made to set up and test a technological product has to be made for supporting the process to bring those products to market, providing an organic sustainable plan and an exploitation strategy. This support includes business strategy, business modelling, marketing, sales, after-sales support, service desks, IT service management systems, supply chain management, staff training and education, business change, and transition. TLR and MRL might be very useful in the process of the market access of a product.

Part of interest: Part of interest: The entire document.

Target groups: RPOs, Business Innovation

→ **Link to the document**

E. Establishing practices and methods for evaluation

This last category of the Toolbox is focused on the transversal and crucial element of the RRI bottom-up demand-driven approach used by CHERRIES, i.e., evaluation and monitoring. What has been described in the various categories of the Toolbox is a complex process of innovation and change that requires to be periodically assessed and monitored, in order to steer its direction towards a more inclusive and sustainable healthcare innovation ecosystem and to overcome possible obstacles and problems. In CHERRIES, a specific challenge for monitoring and evaluation activities concerns the contextualisation of RRI at the territorial level and in healthcare innovation, and the adoption of a co-creation approach also in this field.

Usually, activities, projects, initiatives, are assessed according to criteria like efficiency, efficacy, impact, and sustainability. The resources collected here, identified in the framework of various projects and experiences, present different tailored approaches to assessment and monitoring, adding several other criteria to the four mentioned above.

In the case of CHERRIES (but also of other similar projects), evaluation and assessment have to be applied to three different processes: the project progress in itself; the process of RRI bottom-up demand-driven innovation in healthcare experimented in the three ongoing pilots in Örebro (Sweden); Murcia (Spain), and Cyprus; the process of institutional change for embedding the RRI approach in the innovation process and in the governance of the organisations involved in the pilots. In this regard, a thorough and continuous assessment and monitoring is an important element for a successful governance of the initiative.

These are the reasons why this section of the Toolbox is devoted to monitoring and assessment/ evaluation. The collected resources have been divided into three subcategories:

    E.1. Assessment of the embedment of RRI
    E.2. Assessment of Gender equality in organizations
    E.3. Impact assessment and sustainability.

The first subcategory contains resources focused on the assessment (including self-assessment) of the embedment of RRI approach as a whole, within different kinds of organizations (including research organizations, the Academia, SMEs and industries, higher education institutions, etc), by action plans, road maps.

The second subcategory is focused on gender equality assessment. Gender equality is one of the RRI keys, in which institutional change processes have been promoted and implemented, trying to experiment with different solutions reaching (often) the planned institutional changes. Therefore, solutions, approaches, and methods used for assessing

gender equality and for evaluating projects and initiatives can be useful because they might be also transferred and used successfully in other areas.

The third subcategory includes resources on sustainability and impact assessment. In particular, some resources are focused on sustainability and the contribution of projects and initiatives to the Sustainable Development Goals; other resources present some first approaches in the assessment of territorial RRI to manage territorial challenges and risks; and others contain new approaches and methods for assessing the impacts of research activities.

E.1. Assessment of the embedment of RRI

This first subcategory contains different resources and tools for monitoring and assessing the embedment of RRI in different kind of organisations (such as RPOs, universities and higher education institutions, SMEs and industries, etc.) or for evaluating at what level a project or an innovation process is adopting and implementing RRI keys or dimensions, on the basis of different criteria.

This subcategory is linked with the subcategory A4 Starting the process, of which it represents the further and recurring development. As stated in A4, institutional change and RRI embedment are aimed at creating new institutional space, rules, and norms for a closer exchange between science and society. In this framework, assessment and monitoring are important aspects for assuring the governance processes of research and innovation organisations.

Some of the resources presented were devised and can still be used to accompany the process of institutional change of research organizations (universities, RPOs, higher education institutions, etc.) toward more responsible and inclusive research, for example by the design and implementation of road maps, action plans, grounding actions, etc. Some resources are specifically addressed to SMEs and Industries.

A great part of the resources collected in this subcategory have been devised, used, and promoted by European projects, like MoRRI and SuperMoRRI, RRI Tools, New HoRRizon, Compass, Prisma, Karim, Orbit, STARBIOS2, etc, but there are also some that have been developed in an extra-European project (like InFieri Project, in Canada). Some of these resources are well known, such as the MORRI list of 36 indicators. Most of the resources adopt a formative approach, using self-reflexing tools or matrixes that can be used also periodically for evaluating the institutional change process and reflecting on lessons learned from its implementation. The implementation of assessment methods might require to carry out workshops, meetings, field visits, or the organization of focused living labs. Few resources describe external evaluation procedures. One resource is focused on the relationships between formative and external evaluation.

Among the selected resources, few have a more general character. The first one is a checklist made by UNESCO defining standards for responsible research systems and organisations to be applied in all countries, whose application is also tied to the EU project RRING. The second one is a paper describing the state of art of the reflection on the definition of RRI assessment and evaluation methods and criteria for the projects funded in the framework of HORIZON2020. This reflection – and in particular the assessment of the implementation of "territorial RRI" – is in its initial stage.

Finally, this subcategory contains also few resources specifically focused on the assessment of public and citizen engagement/science education activities.

201. Recommendation on Science and Scientific Researchers (RSSR)

This is a UNESCO document that codifies the goals and value systems by which science operates, adopted by all its member states in November 2017. The UNESCO Recommendation on Science and Scientific Researchers (RSSR) entails ten key priority areas for its global implementation and four-yearly monitoring. They re-affirmed legal commitments to guarantee scientific freedom, ensure public engagement with science, support the 'human right to science', establish equitable and sustainable workforces and pipelines, and many other valuable standards and norms that are meant to guide science equally everywhere. They set out a scientists' bill of rights and agreed on scientists' autonomy, responsibility, freedoms, and minimum working conditions. These standards are now meant to apply to researchers worldwide, whether in public, private, or higher education.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Higher education institutions, CSOs

→ **Link to the document**

202. Introduction – Assessment of Responsible Innovation

This is the Introduction of the book "Assessment of Responsible Innovation. Methods and practices" (by van de Poel, 2020). It explores methods and practices for the assessment of RRI. RRI aims to encourage societal actors to work together during all phases of the research and innovation (R&I) process to better align R&I and its outcomes with the values, needs, and expectations of society. Assessing the benefits and costs of RRI is thus crucial for furthering the responsible conduct of science, technology, and innovation.

Part of interest: The entire article.

Target groups: RPOs, Payors, Innovation Business, Higher education institutions, CSOs

→ **Link to the document**

203. HORIZON 2020 SWAFS Evaluation

The European Commission has started in the framework of the topic H2020-14-2018-2019 a common reflection on evaluation and assessment procedures and methods to be adopted in supporting the development of territorial RRI. The challenge is to set up a shared way to assess territorial RRI impacts. The resource is the presentation by Cristina Morcone (EC officer) at the starting event of this reflection. The presentation describes the project evaluation criteria for excellence, impact (regarding the MoRRI indicators and the Sustainable Development Goals), and implementation.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Higher Education institutions, Policymakers, Payers

→ **Link to the document**

204. Monitoring the evolution and benefits of Responsible Research and Innovation (MoRRI)

EU MoRRI project (carried out from 2014-2018) provides scientific evidence, data analysis, and policy intelligence to support the European Commission in relation to RRI. In particular, MoRRI operationalises the RRI concept and its six keys, develops a sound conceptual framework and associate methodologies; and tests the potential of this methodology to allow monitoring the current state and short-term evolution of RRI. Then, MoRRI defined a list of 36 indicators that have to be applied for assessing the impacts of RRI practices. The link contains the publications of the reports with the indicators. In compliance with the aims of MoRRI, all indicators target the country level, even though most of them are based on data aggregated from the level of institutions or individuals.

Part of interest: The entire document and in particular the list of the 36 indicators.

Target groups: Innovation business, Policymakers, RPOs, Higher Educations Institutions, CSOs

→ **Link to the document**

205. Societal Readiness Level Thinking Tool

The thinking Tool (New HoRRIzon Project, Deliverable D6.1, 2018) offers practical guidance for researchers who wish to mature the societal readiness of their work. The primary goal is to help researchers to align their project activities with societal needs and expectations. The thinking Tool asks reflective questions to stimulate thinking about how to integrate ideas about RRI into research practice, at different stages in the project life.

Part of interest: The entire tool.

Target groups: RPOs (mainly), Innovation Business, Higher Education institutions

→ **Link to the document**

206. RRI Tools Self Reflection Tool

This self-assessment tool is one of the main tools of the RRI Tools platform, which contains also hundreds of resources and documents on RRI (to be used also for training on RRI). For each RRI policy agenda, the Tool includes tailored questions useful for starting a self-reflection, considering who is the respondent (research community, policymakers, education community, business & industry, civil society organisations). The use of the Tool helps the team in designing a process or project in line with RRI principle or for assessing the compliance of their activity/project with the RRI approach. The questions of the self-reflection Tool can be also downloaded, for working offline. The platform contains also a guide on how to use the tool.

Part of interest: The entire tool.

Target groups: RPOs, Innovation Business, Higher Education Institutions, CSOs

→ **Link to the document**

207. The complexity of monitoring and assessing RRI structural change implementation and impact in research organisations within biosciences

This is a paper (by Kalpazidou Schmidt, 2019) on the monitoring and assessment procedures designed and used in the framework of STARBIO2 Project actions plans implemented in biosciences research organisations. Monitoring and assessment criteria were the following: effectiveness, efficiency, relevance, sustainability, transferability, and impact. The assessment and monitoring procedures have been based on a collection of documents and information and of bilateral meetings. The document is Note #12 of the "RRI Implementation in Bioscience organisations" presented in the Guidelines from the STARBIOS2 project.

Part of interest: The entire document.

Target groups: RPOs, Innovations business, Higher education institutions

→ **Link to the document**

208. Nucleus implementation Road Map

The NUCLEUS project focuses on identifying key factors for the successfully embedment of RRI in academic practices. The Implementation Roadmap (Deliverable D3.6, 2017) introduces steps and actions to install 10 embedded Nuclei and 20 mobile Nuclei as innovative and reflective RRI test-beds. NUCLEUS approach foreseen the use of a self-assessment tool by the Nucleus, starting from the beginning of the process and to carry out a SWOT analysis of the situation. Setting up a RRI Nucleus foreseen 8 actions, the last one is devoted to embed ongoing reflection, analyse processes, and procedures for monitoring and evaluating progress during the implementation (phase 8).

Part of interest: See in particular, Pp. 42-43 on monitoring and evaluation; Pp. 63-67 on the use of MoRRI indicators and the appendices.

Target groups: Policymakers, Patients and CSO, RPOs, Innovation Business, Higher Education Institutions, Intermediaries, Providers

→ **Link to the document**

209. Compass responsible Innovation Self Check Tool

The COMPASS Responsible Innovation self-check Tool aims to help Small and Medium-Sized Enterprises in highly innovative sectors to learn how to effectively integrate Responsible Innovation practices (RI) into their company and innovation management. For accessing it is necessary to register. The self-check Tool is described in the paper "The COMPASS self-check Tool. Enhancing organisational learning for responsible innovation through self-assessment".

Part of interest: The entire tool.

Target groups: Innovation Business

→ **Link to the document**

210. PRISMA RRI Exemplar Road Map

This document (2019) provides guidelines to develop long-term strategies (roadmaps) to innovate responsibly, integrating technical, ethical, social, environmental, and economic issues into research and innovation practices. The focus is on transformative and enabling technologies. The road mapping includes 6 steps: commitment and leadership; context analysis; materiality, experiment and engage; validate; road map design. The sixth step on validation is aimed at the evaluation and validation of the added value of the Road map in terms of its impact on the product development and on the company on the basis of some criteria. The resource includes also: the RRI key performance indicators

Part of interest: See in particular, Section 6.6. "Validation", the table on ISO standards and RRI, the list of KPIs, the list of criteria for the evaluation exercise.

Target groups: Innovation business, Start-ups

→ **Link to the document**

211. ORBIT Self-Assessment Tool

The RRI self-assessment Tool for innovation and research organisations can be used as a starting point for an institutional change process. ORBIT set up a Framework to be adopted to include RRI principles in ICT activities of SMEs. The Framework is articulated in four areas: Anticipate, Reflect, Engage, Act − AREA. The Tool is tied with the implementation of the Framework. The Tool requires free registration.

Part of interest: The entire tool.

Target groups: RPOs, Innovation Business

→ **Link to the document**

212. RI In-depth assessment tool

This is the Responsible Innovation RI In-depth Assessment Tool template set up in the framework of the Interreg ROSIE Project for helping the SMEs to reflect on responsible innovation themes, their level of implementation within the organisations, and on the definition of a plan for the improvement of innovation practices to make them more sustainable, socially accountable, and competitive. The tool guides the reflection by providing questions organised according to the EU RRI Policy Agendas: Ethics, Gender Equality, Governance, Open Access, Public Engagement, and Science Education.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Start-ups

→ **Link to the document**

213. The responsible innovation in health tool and the need to reconcile formative and summative ends in RRI tools for business

This paper (by Lehoux, Silva, Oliveira, and Rivard, 2020) is focused on the relationship between formative self-assessment tools and summative external assessment approach in helping entrepreneurs to integrate RRI principles into their practices. Usually, the summative external approach received little attention. This study addresses this gap by applying the Responsible Innovation in Health (RIH) Tool, which adopted an external assessment approach, to 16 health innovations from Canada and Brazil.

Part of interest: The entire article.

Target groups: Innovation business, RPOs, Higher education institutions

→ **Link to the document**

214. The InFieri Assessment Tool for Responsible Innovation in Health

The Responsible Innovation in Health RIH Assessment Tool was developed and validated by InFieri Project to assess responsibility in health innovation. In particular, it might be used by policymakers and providers to assess whether an innovation might be qualified as a Responsible Innovation in Health (RIH). A User Guide has been developed to facilitate the application of the Tool. Drawing on RRI and health policy research, the RIH Tool entails a three-step process assessment of an innovation: screening (with respect of the RIH criteria), assessment of the presence of responsibility features through nine attributes; and rating, determining the outcomes of the assessment with the help of scorecards.

Part of interest: The entire document.

Target groups: Policymakers, Providers, Innovation business, RPOs, Professionals, Patients

→ **Link to the document**

215. Responsibility Navigator

Responsibility Navigator is a self-reflecting tool for supporting decision-makers within research organisation (RPOs, RFOs, Industries, etc) towards more responsiveness and accountability. The tool, set up in the framework of ResAgora Project, supports those decision-makers as 'change agents' to work as 'institutional entrepreneurs', seeking to lead the R&I performed in Europe in the direction of more responsiveness. The Res-AGorA Responsibility Navigator offers support and guidance for reflecting on and intervening in decision making and negotiation processes to fund and orientate R&I activities, whereby these processes can be located within or between organisations.

Part of interest: The entire tool.

Target groups: RPOs, Innovation Business, Payers, Higher education institutions

→ **Link to the document**

216. EDGE Tool on public engagement

This is the Interactive tool to assess the institution's support needs for public engagement, provided by the UK National Co-ordination Centre for Public Engagement. The EDGE Tool was created to help universities assess their current support for public engagement, and to identify areas where they would like to see change. The self-assessment tool identifies three macro areas of public engagement: the area of purpose (including the issues of mission, leadership, and communication); the area of the process (including the issues of support, learning, and recognition); and the area of people (including staff, students and public). The tool identifies also the following dimensions: Embryonic; Developing; Gripping; Embedding.

Part of interest: The entire tool.

Target groups: Policymakers, Providers, RPOs, Business Innovation, High Education Institutions

→ **Link to the document**

217. Citizen science for public health – typology

The resource addresses the central question as to whether citizen engagement in knowledge production could enable inclusive health policymaking. Building on non-health work fields, the authors describe different types of citizen engagement in scientific research, or 'Citizen Science'. The article describes the challenges that Citizen Science poses for public health, and how these could be addressed. The resource provides also a draft framework to enable the evaluation of Citizen Science in practice, consisting of a descriptive typology of different kinds of Citizen Science and a causal framework that shows how Citizen Science in public health might benefit both the knowledge produced as well as the 'Citizen Scientists' as active participants.

Part of interest: The entire document.

Target groups: RPOs, CSOs, Policymakers,

→ **Link to the document**

218. Assessing Patient participation in health policy decision-making in Cyprus

This is a paper (by Souliotis et al., 2016) describing the application Health Democracy Index (HDI) to assess the level of participation of patient associations in policy decision-making in Cyprus. The questionnaire used was comprised of two parts, a socio-demographic section, and the Health Democracy Index. The HDI shows to be efficacy in assessing the participation of patient associations.

Part of interest: The entire document.

Target groups: RPOs, CSOs, Policymakers, Providers, Professionals

→ **Link to the document**

E.2. Assessing gender equality in organisation

Gender equality assessment is an area in which a large number of experiences, studies, analysis, and reflections have been made during the last 10 years. Furthermore, in this regard, many desired and designed institutional changes have been accomplished. These ten years of work on gender equality assessment led to the production of tools and methods that might be transferred also in other areas. For this reason and in consideration of the relevance of gender issues for implementing an inclusive, responsible and sustainable healthcare research and innovation ecosystem, a specific subcategory was devoted to gender equality assessment. It has to be considered that also some of the resources contained in the subcategory E1 on RRI assessment dealt with gender equality.

Most of the resources contain tools and guidelines to assess gender equality in research organisations, providing monitoring tools to be used for promoting and supporting institutional change processes by accompanying the implementation of road maps, action plans, grounding actions, etc. In addition, some resources concern useful self-reflecting tools. Most of the resources have been defined and implemented in the framework of EU projects; one of the tools is taken from GEAR – Gender equality in academia and research, built by EIGE – European Institute for gender equality. Some resources contain action plans or road maps for gender equality. Three resources are also focused on the issue of the assessment of the existing situation in a research organization from a gender equality point of view (gender audit). One of those describes the experience of a survey on gender equality carried out in a research organization in the UK, which is interesting for the items investigated; the second one is a framework questionnaire for gender audit and assessment set up in the framework of the EU project ACT; the third one is a self-reflexive tool of the GRACE project. The last resource contains training material useful for the sustainability of gender equality plans.

These are the resources of this subcategory.

219. LIBRA Guide for faculty evaluation

LIBRA is an EC-funded project which brought together ten research institutes in life sciences in ten European countries that realised ten Gender Equality Plans. In this framework, LIBRA set up a Guide for evaluating the gender situation in Faculty and promoting a fair and gender-inclusive situation. The Guide provides also practical advice to remove gender bias starting from the recruitment process, for raising the number of female scientists in top-level positions.

Part of interest: The entire document.

Target groups: RPOs, Higher Education Institutes, Innovation Business

→ **Link to the document**

220. Gender equality diagnostic tool

The Workplace Gender Equality Agency's ('WGEA' or 'Agency') Gender Equality Diagnostic Tool (2019) helps to analyse the status of gender equality and pinpoint gender equality gaps within an organisation. It can be used with the Gender Equality Strategy Guide to assist with the development of a strategy for addressing inequalities.

Part of interest: The entire document.

Target groups: Policymakers, Patients and CSOs, Providers, RPOs, Innovation Business, Intermediaries, Payers

→ **Link to the document**

221. Gender Equality in Academia and Research – GEAR Tool

The Gender Equality in Academia and Research (GEAR) Tool provides universities and research organisations with practical advice and tools through all stages of institutional change: from setting up a gender equality plan to evaluating its real impact. The tool has been defined by EIGE – European Institute for Gender Equality. The Tool contains also examples and resources. The GEAR foresees the implementation of six steps: 1. Getting started; 2 analysing and assessing the state-of-play in the institution; 3. Setting up a gender equality plan; 4 implementing a gender equality plan; 5. Monitoring progress and evaluating a gender equality plan; 6. What comes after the gender equality plan? A Guide for using GEAR is available on the platform.

Part of interest: See in particular Step 2 and Step 5.

Target groups: RPOs, Innovation Business, Higher Education institutions

→ **Link to the document**

222. GRACE Reflection Tool for RRI Initiatives

This "Reflection Tool" is a six-page document that can be printed and used to facilitate fruitful reflection and discussion on vision, goals, and implementation of RRI initiatives in smaller groups. It was initially developed as part of the GRACE Project where six research performing and funding organisations develop and implement Grounding Actions to strengthen responsible practices in their organisation or network. The Tool can, however, be used by anyone who wants to experiments with such efforts for instance at the beginning of a new project. It is meant to help a working group in its general reflection on what it wishes to achieve, in setting measurable success criteria for the sake of monitoring and evaluation, and in project management by planning the steps of implementation, foreseeing potential obstacles, and reflecting on needed resources.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Higher Education institutions

→ **Link to the document**

223. Triggering institutional change towards gender equality in science

The Guidelines (Trigger Project, Deliverable D7.5, 2017) provided orientations and analyses to manage what may happen when, in a given research organisation, a gender action plan is launched (be it promoted by a specific project team, the HR Department, the Rector, the Head of a department or other internal stakeholders). The Guidelines took into account also a wider debate on institutional change towards gender equality involving representatives of other 8 EC-funded structural change projects. The Guidelines are articulated in four macro-areas: transformational agent; activation and mobilisation; making an impact; and sustainability.

Part of interest: See in particular area #3 "Making an impact" and 4 "Sustainability".

Target groups: RPOs, Higher Education Institute

→ **Link to the document**

224. Measuring Gender in R&I – Theories, Methods, and Experience

This paper (by Palmen et al., 2019) provides an overview of the theoretical assumptions, methods, and key results from the Evaluation Framework for Promoting Gender Equality in Research and Innovation (EFFORTI) Project, which was funded by the European Commission. The purpose of EFFORTI was to analyse the impact of interventions to promote gender equality in research and innovation (R&I) and to establish criteria for more responsible and responsive research and innovation (RRI) systems in Europe. This paper provides an overview of the project's main results and the lessons learned from the empirical analysis of R&I systems in several European countries and a comparison of 19 gender equality intervention measures (case studies). The article summarises the lessons learned and the recommendations for measuring gender equality.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Higher Education institutions

→ **Link to the document**

225. Structural Transformation to Achieve Gender Equality in Science – Guidelines

The document (Stages Project, Deliverable D8.3, 2015) contains a description of action plans for promoting institutional change towards equal opportunity in science and a list of 20 useful recommendations for implementing structural change action plans, articulated in the following areas: collecting data and monitoring gender equality; engaging leadership; policy-making and institutionalisation; networking and empowering women to take action; integrating gender in education and research; communication and visibility.

Part of interest: See in particular recommendations #4 and #5.

Target groups: RPOs, Innovation Business, Higher Education Institution

→ **Link to the document**

226. Markers of achievement for assessing and monitoring gender equity in a UK National Institute for Health Research Biomedical Research Centre: A two-factor model

The article (by Henderson et al., 2020) describes the survey carried out online to assess and monitor significant progress in gender equity (GE) to be eligible to apply for funding in Biomedical Research Centres (BRC). This is the first survey tool designed to rank and identify new GE markers specific to the NIHR BRCs.

Part of interest: The entire document.

Target groups: RPOs, Innovation Business, Higher Education institutions

→ **Link to the document**

227. ACT Gender Equality Audit and Monitoring (GEAM)

The resource has been made in the context of ACT Project and represents the deliverable D2.1. The Gender Equality Audit and Monitoring (GEAM) tool provides an integrated environment for carrying out survey-based gender equality audit in organisations (e.g., university or research performing organisation) or organisational units (faculty, departments). The GEAM tool is based upon the Athena Survey of Science, Engineering, and Technology (ASSET) and on existing measurement scales in the scientific literature. The GEAM tool provides an integrated environment for carrying out survey-based gender equality audits and monitoring that involves a pre-defined set of recommended questions (GEAM Core) and a database for managing and sharing newly developed or adapted questionnaires.

Part of interest: The entire document.

Target groups: RPOs, Higher Education institutions

→ **Link to the document**

228. Report on Strategic Advice for enhancing gender dimension of Open Science and Innovation policy

The present report, prepared within the framework of H2020 GENDERACTION Project, explores the possible intersections between gender and Open Science/Open Innovation, and should be considered as a starting point for stakeholders to reflect on how the two ERA priorities may create reinforcing synergies. The report also underscores the need for further studies and analyses. The report contains data on the situation of Open Science and Open innovation from the gender point of view. The document contains also recommendations. The third and fourth recommendations are related to gender equality assessment in RPOs and RFOs.

Part of interest: See in particular the part on recommendations.

Target groups: Policymakers, RPOs, Innovation Business, Intermediaries, Payers

→ **Link to the document**

229. Gender Equality Academy – a Portal on training and resources

The Gender Equality (GE) Academy Project is developing and implementing a high-quality capacity-building programme on gender equality in research, innovation, and higher education for researchers, managers, administrators, HR managers, and academics staff. The project promotes different kinds of training and capacity-building initiatives (composed of tailor-made training materials) aimed at increasing the skills or deepening the expertise of people involved in implementing measures towards gender equality in their institutions. Among the issues of the training, there are: the definition and implementation of a Gender equality plan; gender bias; recruitment and promotion of women leadership; gender in research content; intersectionality; the role of men; Gender equality plan and RRI; sustainability of Gender equality plan, etc. Among the resources, there is the Deliverable "D2.1 Inventory of key resources" including Area 8 specifically focused on "Setting indicators, monitoring, and evaluation" (Pg. 148-170). Training initiatives, as well as the available resources, can accompany and support the institutional change process and contribute to its sustainability.

Part of interest: The entire website, and in particular the pages Repository, Deliverables, Past training, and Future offer.

Target groups: Policymakers, CSOs, RPOs, Innovation business, intermediaries, Higher education institutions

→ **Link to the document**

E.3. Impact assessment and sustainability

This final subcategory of the Toolbox is focused on the complex issues of the impact assessment of research and innovation initiatives: projects and interventions; policies; institutional change processes, etc. Impact assessment plays an important role also to guarantee the sustainability of the promoted changes or interventions or innovation proposed.

As shown by some of the resources collected here, the issue of sustainability requires to be taken into account since the beginning of the research and innovation activities.

On the basis of the characteristics of CHERRIS approach, this subcategory presents methods of assessment to investigate diverse domains of impacts.

The first area of resources is focused on sustainability. The 2030 Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, "provides a shared blueprint for peace and prosperity for people and the planet, now and into the future". At its heart, there are the 17 Sustainable Development Goals (SDGs − https://sdgs.un.org/goals), which are an urgent call for action by all countries for a global partnership. This first group of resources contains tools (also self-reflexive tools) for assessing the impact with the respect to the 17 United Nations SDGs. Most of the EU projects are requested to contribute to the SDGs. Most of the resources of this group are specifically addressed to industries and SMEs.

The second group of resources describes methods and approaches for assessing the implementation of territorial RRI initiatives. One should note that the promotion of projects and initiatives aimed at embedding the RRI approach in the governance of territory to manage territorial challenges and risks is a fairly new development. These resources provide some first examples of methods (a different one from the other) for assessing RRI impacts (see the experiences of SeeRRI, TeRRItoria, Transform, etc.). These projects are also tied with the implementation of the UE Smart Specialisation Strategy (S3) in each UE region. Two resources are also focused on the assessment of the implementation of S3.

The last group of resources contains reflections and methods on how to assess and measure the impact of research activities (in general and with a focus on health) on the wellbeing of people and communities. The literature on research impact assessment (RIA) is rather abundant, so the resources collected here have been chosen for their innovativeness and because they have been taken into account in the definition of CHERRIES evaluation approach.

What follows are the resources of this subcategory.

230. Sᴅɢ Impact Assessment Tool

The SDG Impact Assessment Tool is a free online learning tool that visualizes the results from a self-assessment of how an activity, organisation, or innovation affects the SDGs. It aims to stimulate the user to get a better understanding of the complexity of sustainable development and the different aspects of the SDGs and to support the user in prioritizing actions.

Part of interest: The entire tool.

Target groups: Business Innovation, RPOs, CSOs, Policy Makers

→ **Link to the document**

231. Sᴅɢ Action Manager

This is a Tool on Impact Management for the Sustainable Development Goals for Business organisations. Access to the Tool requires free registration.

Part of interest: The entire tool.

Target groups: RPOs, Innovation business, Intermediaries

→ **Link to the document**

232. B-Impact Assessment

This is a tool a company can use to measure its impact on its workers, community, environment, and customers. The Tool provides a certification. The use of the Tool foresees three steps: 1 step, assess the impact of the organisation with regard to the following impact areas: governance, workers, community, and environment); step 2: share the results with teams and compare the impact with that of other organisations; step 3: improve the impact by designing a road map, taking into account the answer about the impact of the organisation. The website contains examples and case studies.

Part of interest: The entire tool.

Target groups: RPOs, Innovation business, Intermediaries

→ **Link to the document**

233. Tʜᴇ global standards for sustainability Reporting

This is a platform set up by the Global Reporting Initiative Standards, aimed at creating a common language for organisations – large or small, private or public – to report on their sustainability impacts in a consistent and credible way. In addition to reporting companies, the standards contained in the platform are highly relevant to many other groups, including investors, policymakers, capital markets, and civil society.

Part of interest: The entire report and in particular the standard.

Target groups: RPOs, Innovation Business, CSO, Payers, Policymakers

→ **Link to the document**

234. KARIM Assessment Matrix

This is a RRI self-assessment tool set up in the framework of KARIM project. The Karim assessment Matrix helps entrepreneurs and innovators to gain insight into where they are concerning the social, environmental, and economic impact of their companies and how they have organised their processes. Applying it to the research and innovation process(es) of an enterprise, it will allow to know the strengths. Moreover, the areas in which it can make progress are pointed out. This will help innovators to decide the area of improvement. The Matrix foresees four steps: selection of relevant topics; description of the situation; possible improvements; identification of possible obstacles; needed resources. Filling the matrix requires around 4 hours.

Part of interest: The entire tool.

Target groups: RPOs, Innovation Business, Start-ups

→ **Link to the document**

235. Smart Specialisation Evaluation

The report presents a set of preliminary conceptual and practical considerations on the evaluation of the Smart Specialisation policy. It opens a discussion that aims to set the scene for more articulated and detailed reflections. This is one of the official Guides to evaluate RIS3 policies.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Higher Education Institutions, Innovation Business, CSOs

→ **Link to the document**

236. RIS3 Assessment Wheel – A synthetic tool to position yourselves and your RIS3

The Wheel is a tool of the RIS3 Guide. It presents a system for the synthetic representation of the progress made in drafting/designing a RIS3 that allows condensing a huge amount of information in one visual modality.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Higher Education Institutions, Innovation Business, CSOs

→ **Link to the document**

237. SeeRRI Plan for activity evaluation

This document (SeeRRI project, Deliverable D6.1, 2020) provides information on the design methods for evaluating the SeeRRI project activities and the framework for self-sustaining ecosystems in terms of: Outcomes of the activities initiated in the three territories affiliated to the SeeRRI Project; Societal, democratic, environmental, economic and scientific impacts of activities in the territories; Recommendations on policy and governance structures to facilitate the creation and maintenance of self-sustaining RRI ecosystems.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Innovation business, CSOs

→ **Link to the document**

238. Transform – Assessment and Monitoring guide

This is the Deliverable D7.1 of the Transform Project. It provides a first set of instruction and advice on the monitoring and assessment of embedding the principles and practices of RRI – Responsible Research and Innovation – into institutions, policies, and practices of innovation at the regional scale. The project involves itself in processes of innovation, policy-making, and practice in three European regions: Lombardy, Catalonia, and the Brussels-Capital Region.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Innovation business, Intermediaries, Higher education institutions, Payers

→ **Link to the document**

239. TeRRItoria Evaluation Scheme

This is the first evaluation scheme set up by the TeRRItoria project (Deliverable D6.1.). This scheme is being up-dated and tailored with respect to the content of the five on-going TeRRItoria experiments (TE) of implementation of RRI approach at the territorial level. By bringing together a wide range of stakeholders in the development and implementation of the five experiments, the project intends to address and mitigate territorial R&I challenges through the advancement of "Territorial RRI". Overall, the internal evaluation of activities is designed to assess the implementation of TE actions/initiatives and their impacts produced throughout the project and to use this knowledge to ensure the long-term sustainability of the experimental activities commenced.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Innovation business, Intermediaries, CSOs, Payers

→ **Link to the document**

240. ASIRPA: A comprehensive theory-based approach to assessing the Societal Impact of a research organization

This is a paper (by Jolyet al., 2015) describing the ASIRPA approach for assessing the socio-economic impact of RPOs through case studies. This approach has been set up and used in the framework of ASIRPA (Socio-Economic Analysis of the Impacts of Public Agricultural Research) project. The cases are theory-based, selected to characterize the diversity of the broader impacts, and standardized to allow the scaling-up of the analysis of the impact to the level of the organisation.

Part of interest: The entire document.

Target groups: RPOs, Innovation business, Policymakers, Payers, CSOs, Higher Education Institute, Providers

→ **Link to the document**

241. Developmental Evaluation

This is an article (by Patton, 1994) describing, also with examples, the approach of the developmental evaluation, applied to policies, projects, interventions. This is the definition of Developmental evaluation: Evaluation processes and activities that support program, project, product, personnel and/or organisational development (usually the latter). The evaluator is part of a team whose members collaborate to conceptualize, design, and test new approaches in a long-term, on-going process of continuous improvement, adaptation, and intentional change. The evaluator's primary function in the team is to elucidate team discussions with evaluative data and logic and to facilitate data-based decision-making in the developmental process.

Part of interest: The entire document.

Target groups: Policymakers, RPOs, Higher Education Institutions, Innovation Business, CSOs

→ **Link to the document**

242. Contribution mapping: A method for mapping the contribution of research to enhance its impact

This is a paper (by Kok, and Schuit, 2012) describing a new method for assessing and enhancing the impact of health research. Contribution Mapping is inspired by a perspective from social studies of science on how research and knowledge utilisation processes evolve. For each research project that is assessed, a three-phase process map is developed that includes the main actors, activities, and alignment efforts during research formulation, production, and knowledge extension. The approach focuses on the actors involved in, or interacting with, a research project (the linked actors) and the most likely influential users, who are referred to as potential key users.

Part of interest: The entire document.

Target groups: RPOs, Innovation business, Providers, Professionals, CSOs, Policymakers

→ **Link to the document**

CHERRIES Partners