PRISMA RRI-CSR Roadmap

Deliverable 5.2

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List of abbreviations

<PRISMA>	<Piloting RRI in Industry: a roadmap for tranSforMAtive technologies>
< RRI >	< Responsible Research and Innovation >
< CSR >	<Corporate Social Responsibility>
< LCA >	<Life Cycle Assessment>
<SMEs>	< Small or Medium-sized Enterprise >
<KPIs>	< Key Performance Indicators >
<TRM>	< Technology Road-Mapping>
<IPRM>	< Innovation Policy Road-Mapping Methodology >
<R&I>	< Research and Innovation>
<R&D>	< Research and development >
<ELSI>	< Ethical, Legal, Social Impacts>

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EXECUTIVE SUMMARY

The overarching goal of the PRISMA project is to help companies implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies, and to provide evidence on how RRI can improve their innovation processes and products and help companies to gain trust from society and build resilience, thus strengthening their position on the market.

Research and Innovation (R&I) constantly lead to the development of new technologies, that can have significant impact on people's everyday life, the communities and territories, the whole economy and society. The more these technologies enable improvements or change paradigms, the greater can be their impacts. RRI provides a way to address the needs and concerns of people and society and to develop processes, products and services aiming to positive societal impacts, guiding innovation towards sustainable development goals.

Based on the experience in eight pilots with companies active in different sectors and technologies, PRISMA developed a practical guideline for companies aiming to strengthen consideration of ethical, legal and social impacts (ELSI) aspects in their technology and product development roadmaps. The RRI principles of *anticipation and reflection, inclusiveness, responsiveness* are considered.

The specific RRI pilot roadmaps developed for each of the pilot companies involved in the project were tailored to define a strategy that fits with the features of the company and the specific sector in which it operates and with the aim to improve the societal value and the overall performances of their products. Some RRI actions have been experimented during the two-years of cooperation with the pilots others are indicated in the template of pilot RRI roadmap for future implementation.

The methodology to build a roadmap to integrate RRI in business strategies, is described in part A of the document (PRISMA exemplar RRI roadmap). Case studies are illustrated in part B (PRISMA pilots RRI roadmaps), describing the company specific RRI roadmaps developed for each of the eight PRISMA pilots.

The exemplar roadmap has been developed taking into account ISO and CEN standards regarding management systems in the areas of social responsibility, sustainability, innovation, quality and risks, such as ISO 26000, ISO 31000, ISO 9001 and ISO 56000.

RRI provides a complementary approach compared to existing Corporate Social Responsibility (CSR) practices, adding a specific focus on the R&I process.

The theme of Responsible Research and Innovation has been debated in recent years mainly from the academical or institutional point of view, but there have been still limited initiatives looking at the peculiar organizational, strategic and innovation and economical aspects of RRI implementation in companies.

The PRISMA exemplar roadmap is structured on a set of acknowledged RRI principles, that are operationalized based on three key actions:

1. Integrate analysis of ethical, legal and social impacts since the early stages of product development (reflection and anticipation)
2. Perform stakeholder engagement to inform all phases of product development (Inclusiveness)
3. Integrate monitoring, learning and adaptive mechanisms to address public and social values and normative principles in product development (responsiveness)

These actions are considered as a minimum requirement for RRI implementation. In the RRI exemplar roadmap, each of them is further detailed by examples of more practical sub-actions.

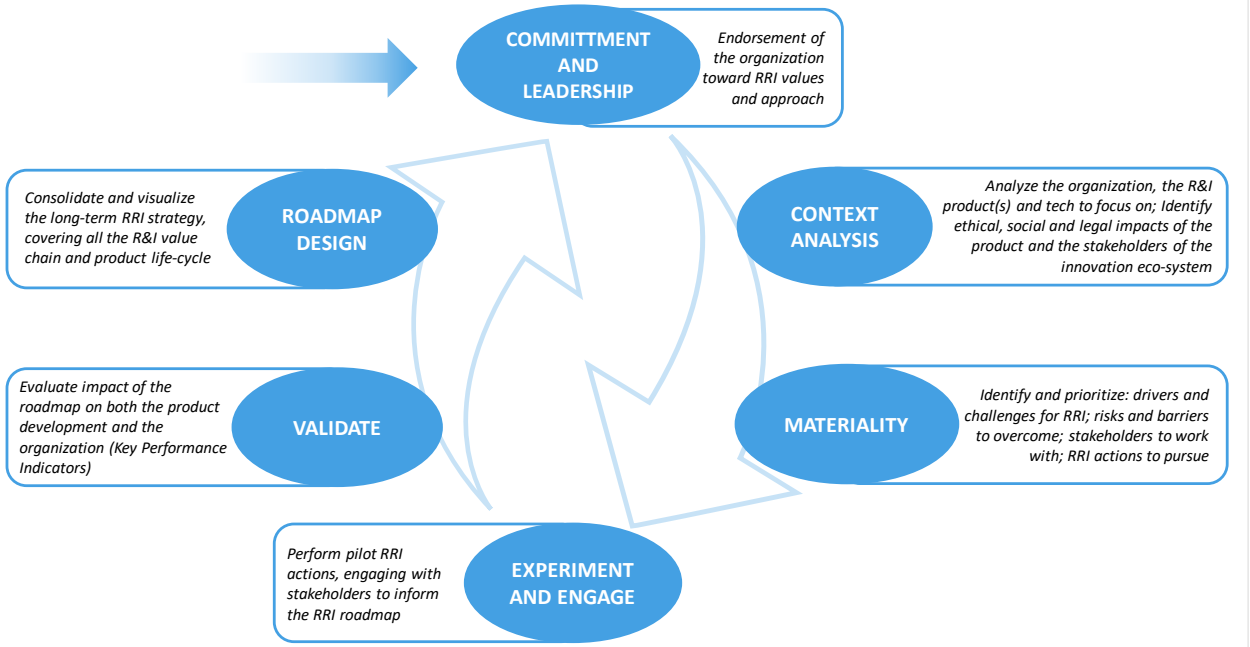
Technology Road-Mapping (TRM) is a strategic planning methodology, already used in the industrial context. It consists in the visualization of the strategic aims of an organization and it can be utilized to structure the

research, development and business activities. In recent years, an Innovation Policy Road-mapping Methodology (IPRM) has been developed to connect industrial developments to societal needs and expectations.

The PRISMA exemplar RRI roadmap, adapts the architecture of the generic IPRM and guides the company in the design of its specific roadmap for the implementation of RRI. It follows a circular process, based on six steps, referring to the RRI principles mentioned above, which can be repeated until the final specific RRI roadmap for the company is completely defined.

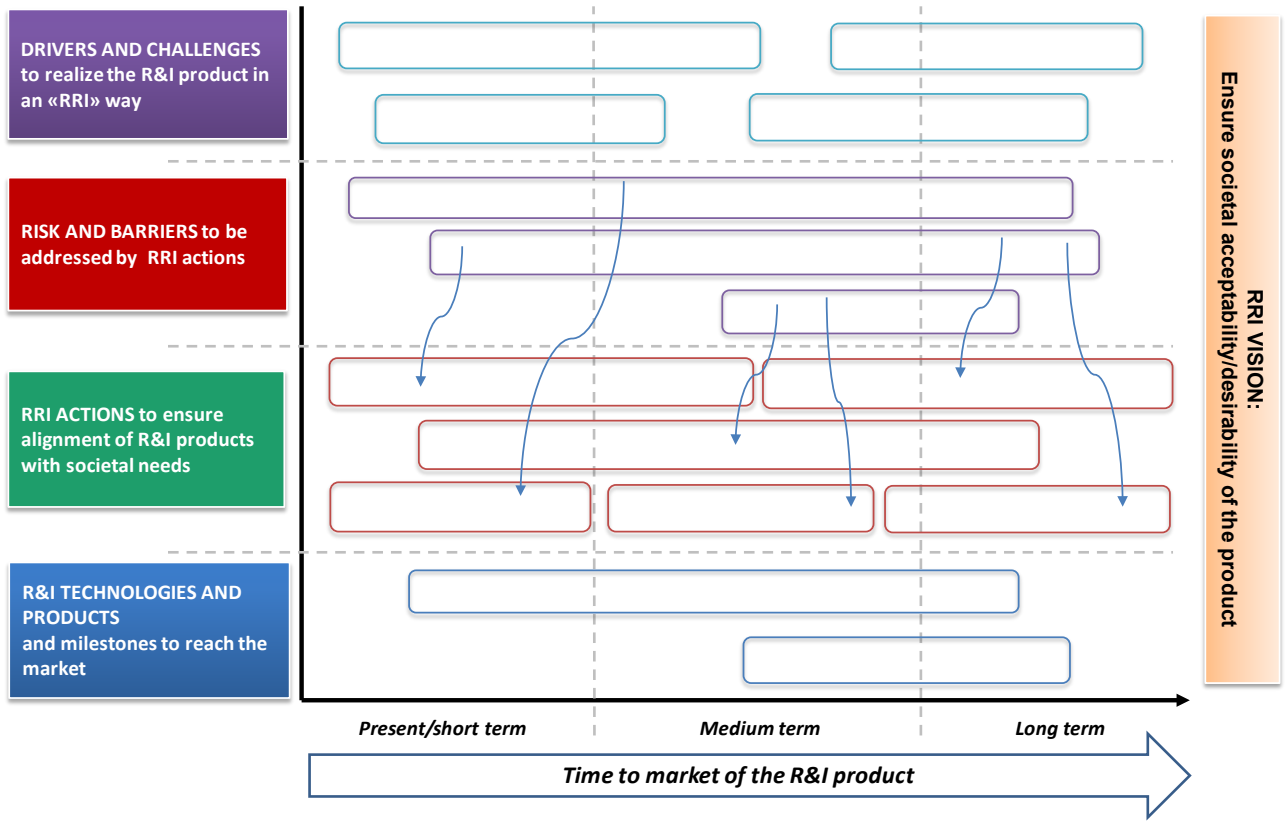
As shown in the figure below, these steps are: top management commitment and leadership, context analysis, materiality analysis, experiment and engagement, validation and the roadmap design.

The final RRI roadmap synthetizes into a graphical map the relevant aspects emerged during the road-mapping process, in particular the RRI vision and the action plan for RRI uptake, as shown by the template below. This map facilitates sharing and communication activities with both internal and external stakeholders.



The six steps of the exemplar RRI/CSR Roadmap methodology

Part A provides also practical examples of RRI actions referred to each RRI principles, criteria and methods for the evaluation of their impacts, tools for the materiality and stakeholder analysis, methodologies for stakeholder engagement, and a SWOT matrix of RRI implementation in the industrial context, based on PRISMA experience.



The PRISMA RRI roadmap template

The pilots were conducted with companies operating in different sectors which are currently driven by transformative technologies, such as: nanotechnologies, synthetic biology and biotechnology, internet of things, drones and autonomous vehicles. The organizations involved include small and medium companies, and a public-private cooperative R&I project.

The description of each of the eight PRISMA pilots is reported in part B. This includes information on the company, their commitment and motivations, a description of the R&I project and the product selected for RRI implementation, the technological, market and regulatory context, the significant ethical, legal and social issues identified, the RRI actions performed during PRISMA, the criteria for impact analysis of RRI uptake (costs & benefits) and the details of the RRI roadmap.

During the pilot, the PRISMA partners have supported the companies in implementing RRI actions adopting two different strategies. By providing external advice and consultancy to the company during the design of its specific RRI roadmap or by having an embedded ethicist within the company co-operating with the different organization's functions. Cornerstones of this action were:

- Performing ethical analysis, to reflect on ELSI of the R&I project
- Realizing awareness-raising and training initiatives for R&D personnel
- Design for values, value scenarios to inform R&I products design
- Advising on implementation of RRI and CSR tools and methodologies
- Organizing dialogues and co-creation initiatives with stakeholders
- Engaging with business partners to address RRI aspects

The technology and sector, RRI vision and key ethical, legal and social impacts addressed by the pilots are synthetized in the table below.

Company	Sector, technology	RRI vision	Significant ethical, legal and social impacts addressed
Colorobbia Consulting	Nanotechnologies, Healthcare	Realize a personalized and point of care therapy, for a highly effective, accessible and affordable treatments of severe diseases	Product efficacy and safety, risk perception and user acceptability, patient's rights (precaution, safety, beneficence, dignity, informed consent, data ownership, transparency
Laboratori Archa	Nanotechnologies, cosmetics and medical devices	Create nano-based dermo-cosmetics products, based on ethically acceptable and sustainable production methods and safe and more effective use of natural and organic ingredients	Product efficacy, safety and safe production, risk perception and user acceptability, improved quality, affordability, compliance with sustainability norms, information to consumers
Evolva	Synthetic biology for healthcare and nutrition	Create a mutual understanding of a desirable innovation pathway that can benefit both the synthetic biotechnology value chain as well as other stakeholders	Safety of genetically modified organisms, value chain/benefit sharing, environmental sustainability, information to consumers
Spectro	Internet of Things for public health and hygiene applications	Develop new cleaning technologies that contribute to public health and hygiene (and respect other relevant values) and offers the possibility to increase market share	Public/patient health and hygiene, sustainability, privacy, security, transparency, autonomy, reliability and trust
Aerialtronics	Internet of Things for Unmanned Aerial Vehicles (UAVs)	Developing drones, combine data collection and AI, ensuring safety, and safeguarding users' rights, including privacy and fair use of data.	Safety, security, and users' rights, including privacy, data protection, and data ownership
HAT	Internet of Things online applications for data sharing	Develop distributed data platform as a mechanism for increased personal control of data	Information privacy, data ownership, commercial use of private data, respect of users' rights, transparency, security.
RDM	Autonomous vehicles for smart cities	Developing automated and personalized public transport to reduce traffic, pollution and parking land use in urban areas	Information privacy, commercial use of private data, and urban planning, safety
BISIGODOS	Syn bio for algae feedstocks production for consumer and industrial sectors	Developing bio-based (algae) feedstock to replace petrol-chemicals, based on RRI-aware LCA	Environmental and social and economic impact, open innovation, transparency

The Prisma experience helped pilot companies to evaluate the most significant ethical, legal and social impacts expected by the development of their products and to identify operative actions to address them.

Normative issues addressed across pilots included privacy, data ownership, safety, efficacy and reliability, transparency and open access, democratic participation and consent (on technological decisions), distribution of benefits, risk and harm, and sustainability and social responsibility.

Early identification of societal needs and concerns helped in designing products that will be better aligned with societal expectations and thus could gain more acceptability by the end-users. Engagement with R&I partners, supply chain actors, regulators, authorities, certification bodies, market operators, clients and end-users (e.g. patients, local communities, consumers, etc.) has been essential to identify in the early stages of the development research opportunities, product design improvements and solutions, ways to address potential regulatory barriers.

RRI can be helpful to anticipate social or market trends or requirements, technological scenarios, possible regulatory changes and thus inform the overall business strategy and help to save money and time. RRI is considered crucial also to build trust and legitimacy, and the companies involved in PRISMA pilots specifically asked for instruments to make RRI implementation more recognizable by the society.

PRISMA experiences showed also that several actions addressing so called RRI principles and dimensions were already part of the usual business practices, at least for some of the pilot companies, though they were not classified as such (*de facto* RRI). However, a structured and strategical approach to responsibility in research and innovation was in most of the cases missing.

The PRISMA analysis shows there are significant barriers for RRI uptake, including the lack of expertise, limited resources, challenges to commit all functions within the company and the project partners and value chain actors, unclear added value of RRI approaches, lack of long-term vision.

The application of transformative technologies typically implies a certain degree of uncertainty both from a technical and societal point of view and thus is the initial driver for companies to look at RRI approaches. However, the reasons why a company could decide to apply a structural and long-term approach to RRI are much broader, there is a complexity of reasons and factors influencing the choice of a company, often not related to the specific technology concerned.

The PRISMA experiences shows that RRI implementation is context-sensitive, depending from the sector, technology, type of company and business. RRI actions involves different company functions, and could have both tangible and intangible, short and long-term impacts at different levels.

In this report, a methodology to develop a vision and an RRI action plan is envisaged, based on the case-by-case and expert-driven approach of PRISMA. The added value of this road-mapping process, is to equip companies with a practical and effective way to bring RRI into their innovation process, whatever are their sector or dimensions and their knowledge about RRI practices. The PRISMA roadmap could help companies to introduce structural changes in their usual business practices, toward more anticipatory, inclusive and responsive research and innovation practices.

INTRODUCTION TO THE DELIVERABLE 5.2

This report provides a practical guideline for companies aiming to strengthen consideration of ethical, legal and social impacts aspects in their technology and product development roadmaps, and a synthesis of experiences, good practices and references resulting from the activities of the European project PRISMA: piloting Responsible Research and Innovation in Industry.

It is addressed to all organisations/agents involved in planning and performing research and innovation and technological development. The focus is on transformative and enabling technologies, and in particular the ones used by the pilot companies involved in PRISMA: nanotechnologies, synthetic biology, internet of things and autonomous vehicles.

The report is divided in two parts:

- **Part A provides a methodology to develop a roadmap to integrate RRI in business strategies, aligned with technology road-mapping at company and product level**
  The methodology includes: consideration of ethical principles for technology development, selection of RRI actions suitable for companies acting in different sectors and technologies, good practices for both consideration of gender and diversity aspects and stakeholder engagement, criteria and tools for analysis of impacts of RRI implementation (cost-benefits), motivation for companies to engage with RRI. The roadmap has been developed taking into account ISO and CEN standards regarding management systems in the areas of social responsibility, sustainability, innovation, quality and risks, such as ISO 26000, ISO 31000, ISO 9001 and ISO 56000. It is thus aligned, to the extent possible, with company practices in these areas.

- **Part B includes good practices examples as models for RRI uptake in companies, based on the work performed with PRISMA pilots and the experience gained during the five stakeholder dialogues organized during the project**
  The case description includes information on the company, their commitment and motivations, a description of the R&I project and the product selected for RRI implementation, the technological, market and regulatory context, the key ethical, legal and social issues identified, the RRI actions performed during PRISMA, the criteria for impact analysis of RRI uptake and the details of the RRI roadmap developed for each of the pilots.

This report is one of the final deliverables of PRISMA, integrating results and experiences of most of PRISMA actions about RRI implementation in companies, and in depth analysis of RRI and CSR literature.

In particular, the following PRISMA experience and results have been considered:

- WP1: inventory of RRI approaches for companies and workplans for the PRISMA pilots, reported in D1.1 and D1.2
- WP2: experiences with RRI implementation in eight industrial pilots – interim and final reports on the pilots (reported in D2.1, D2.2, D2.3 and D2.4)
- WP3: assessment and comparative analysis of pilots (reported in D3.1, D3.2 and D3.3)
- WP4: results of four PRISMA stakeholders dialogues on RRI in industry (reported in D4.1 and D4.2)
- WP5: Analysis of conditions for success of RRI uptake by industry (reported in D5.1)
- WP6: Interviews and documentation produced for the PRISMA Massive Open Online Course (MOOC) on ”Responsible Innovation: Building Tomorrow’s Responsible Firms” that will be published in the edX platform[1]

[1] See details on the course at: https://www.edx.org/course/building-tomorrows-responsibly-innovative-firms

A search of relevant literature and projects has been undertaken, also based on WP1 references, with a focus on implementation of RRI in companies. This has been complemented by use of selected references from literature on corporate social responsibility, in order to integrate the limited information available from the RRI field.

The outcomes of the report, and in particular the RRI actions and criteria for impact analysis, have been reviewed in group discussion with stakeholders and the Advisory Board during one of the PRISMA stakeholder dialogue (Oct 30-31, 2018, Milan).

PART A: PRISMA RRI EXEMPLAR ROADMAP

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TITLE

Guidelines to develop a roadmap to integrate Responsible Research and Innovation (RRI) in industrial strategies

INTRODUCTION

Responsible Research and Innovation (RRI) addresses the development of products and processes that are safe, ethically acceptable, and responding to the needs and expectations of people and the society.

The essential difference of RRI with existing practices on CSR (Corporate Social Responsibility), risk, and quality management, is the focus on the ethical and social impacts during the research and innovation process, from the early stages to prototyping and go to market.

The initiatives to put in practice RRI in industry, for instance in the form of action plan, are still limited, most of them being related to cooperative projects within EU framework programs or national equivalents. Examples include projects such as Responsible Industry, Compass, Smart Map, Liv-In, Orbit.

The present guidelines have been developed by the PRISMA project, taking advantage of eight industrial pilots dealing with the application of transformative technologies in different sectors. The pilots were used to integrate RRI principles in their strategies and actions, in order to improve the societal value and overall performances of the outcomes of their R&D (Research & Development) activities, and develop specific 'pilot RRI roadmaps".

For an effective RRI uptake it is essential to identify strategies and practices that fit with the realities and constraints in which the specific company operates. The PRISMA roadmap aims to do this.

At industry level, Technology Road-mapping is already a quite widely utilized method in strategy planning. A Technology Roadmap consists in the visualization of strategic aims (vision/development plans) of the organization and can be utilized to structure the research, development and business activities. In recent years, the concept of IPRM (Innovation Policy Road-mapping Methodology) has been developed to connect the development of technologies and innovations to a wider societal sphere[2]. A main aspect of IPRM is to identify those societal needs which create a potential demand for new solutions and possibly favour the emergence of new products and markets. IPRM integrate a foresight exercise on enabling technologies, applications, products, markets with analysis of socio-economical and sectorial drivers, and policy and regulatory tools and strategies.

The RRI roadmap proposed in this guideline adapts the architecture of the generic IPRM to the definition of long-term visions and action plans for uptake of RRI within innovation strategies of companies. It provides the methodological and technical conditions to address RRI principles in the context of rapid (and possibly disruptive) scientific and technological developments, to ensure their relevance to society.

This document provides the methodological and technical conditions that characterize the PRISMA RRI roadmap.

In order to facilitate its possible future transferring into the standardisation system, if required by market players, the roadmap is structured to be consistent with the typical standardisation (CEN/ISO) deliverables.

[2] Ahlqvist, T., Valovirta, V., & Loikkanen, T. (2012). Innovation policy roadmapping as a systemic instrument for forward-looking policy design. Science and Public Policy, 39(2), 178-190

1. SCOPE

This document provides a framework to develop long-term strategies (roadmaps) to innovate responsibly, integrating technical, ethical, social, environmental, and economic issues into research and innovation practices, to improve the ethical and social impacts of final marketable outcomes.

The document is addressed to all organisations/agents involved in planning and performing research and innovation and technological development. The focus is on transformative and enabling technologies.

This document has been designed to be consistent, as far as possible, with existing management system standards and with management/governance standards (e.g. ISO 9001). Particular attention has been paid to social responsibility, i.e. ISO 26000.

2. NORMATIVE REFERENCES

The list of existing management standards and normative referenced in the document is given below. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ISO 26000 Guidance on social responsibility
- ISO 31000 Risk management – Guidelines
- ISO 45001 Occupational health and safety management systems-Requirements with guidance for use
- EN ISO 9001 Quality management systems – Requirements
- Series CEN/TS 16555 Innovation Management
- Series CWA 17145 Ethics assessment for research and innovation
- IWA 26 Using ISO 26000:2010 in management systems
- UNI/PdR 27 Guidelines for management and processes development for responsible innovation
- UNI/PdR 18 Social responsibility in organizations - Guidance to the application of UNI ISO 26000
- ISO/DIS 56000 Innovation management -- Fundamentals and vocabulary
- ISO/FDIS 56002Innovation management -- Innovation management system -- Guidance

3 TERMS AND DEFINITION

For the purposes of this document, the following terms and definitions apply.

3.1 ethics: is the systematic reflection on right and wrong conduct according to norms and values that we believe should be followed. Ethics refers to duties, responsibilities, rights, welfare, justice and the avoidance of harms. Typical moral values include autonomy, freedom, dignity, privacy, justice, well-being and responsibility [Series CWA 17145].

3.2 framework: an outline, or skeleton of interlinked items and actions which supports a particular approach to a specific objective, and serves as a guide that can be modified as required by adding or deleting items

3.3 human-centered Design (HCD) is characterized by:

- The design is based upon an explicit understanding of users, tasks and environment;
- Users are involved throughout design and development;
- The design is driven and refined by user-centered evaluation;
- The process is iterative;
- The design addresses the whole user experience;
- The design team includes multidisciplinary skills and perspectives.

[ISO 9241-210 :2010]

3.4 impact assessment: is the assessment of research and innovation for its projected or actual societal impacts [Series CWA 17145]

3.5 management system: set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning, and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

[ISO/TMB/JTCG Joint technical Coordination Group]

3.6 materiality: identification and understanding of priorities with respect to the context of social responsibility in which an organization operates. Priorities thus determined reflect the economic, social and environmental factors that deserve to be considered.

[UNI/PdR 18 Social responsibility in organizations - Guidance to the application of UNI ISO 26000]

3.7 organization: person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

[ISO/TMB/JTCG Joint technical Coordination Group]

3.8 participatory design: is a "practice of collective creativity" that emphasizes active involvement by the users and all the stakeholders in design and development of new systems [Niemelä M., et al. 2014]

3.9 process: set of interrelated or interacting activities which transforms inputs into outputs

[ISO/TMB/JTCG Joint technical Coordination Group]

3.10 performance: measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, processes, products (including services), systems or organizations.

[ISO/TMB/JTCG Joint technical Coordination Group]

3.11 responsible research and innovation (RRI): 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)

3.12 roadmap: is a strategic plan that defines a goal or desired outcomes, and includes the major steps or milestones needed to reach it.

3.12 roadmapping exercise: is a collaborative learning process and a tool for drawing up strategies, reaching consensus on requirements and needs, driving proactive planning and futures studies (VTT)

3.13 risk: effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats.

Note 2 to entry: Objectives can have different aspects and categories, and can be applied at different levels.

Note 3 to entry: Risk is usually expressed in terms of risk sources , potential events , their consequences and their likelihood

[ISO 31000:2018 Risk management — Guidelines]

3.13 risk assessment: overall process of risk identification, risk analysis and risk evaluation

3.15risk identification: process of finding, recognizing and describing risks

3.16 risk analysis: process to comprehend the nature of risk and to determine the level of risk

3.17 risk evaluation: process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable

[ISO Guide 73:2009 Risk management – Vocabulary]

3.18 social responsibility: responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behavior that:

- contributes to sustainable development, including health and the welfare of society;
- takes into account the expectations of stakeholders;
- is in compliance with applicable law and consistent with international norms of behavior; and
- is integrated throughout the organization and practiced in its relationships.

NOTE 1 Activities include products, services and processes.

NOTE 2 Relationships refer to an organization's activities within its sphere of influence.

[ISO 26000:2010]

3.19 Corporate social responsibility (CSR)*:* has been defined as “a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis”, as well as “the responsibility of enterprises for their impacts on society” [European Commission, 2011].

3.20 stakeholder: individual or group that has an interest in any decision or activity of an organization

[ISO 26000:2010 Guidance on social responsibility]

3.21 technology assessment (TA): is a scientific, interactive and communicative process which aims to contribute to the formation of public and political opinion on societal aspects of science and technology [TAMI, 2005]

3.22 top management: person or group of people who directs and controls an organization at the highest level

Note 1 to entry: top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the management system covers only part of an organization then top management refers to those who direct and control that part of the organization.

[ISO 9000:2015]

3.23 usability: is the extent to which specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use [ISO/IEC 1998] can use a product

3.24 user-centered design (UCD) is an approach to interactive system development that focuses specifically on making systems or applications easy to use [ISO/IEC 13407, 1999]

3.25 user committees: This method involves users and other stakeholders in the formal monitoring and steering of the research and innovation process. Typically, there is a kick-off, a mid-term, and a final workshop [Engage2020 Project, 2014]

3.26 context of the organization: combination of internal and external issues that can have an effect on an organization's (3.2.1) approach to developing and achieving its objectives (3.7.1)

Note 1 to entry: The organization's objectives can be related to its *products* (3.7.6) and *services* (3.7.7), investments and behaviour towards its *interested parties* (3.2.3).

Note 2 to entry: The concept of context of the organization is equally applicable to not-for-profit or public service organizations as it is to those seeking profits.

Note 3 to entry: In English, this concept is often referred to by other terms such as "business environment", "organizational environment" or "ecosystem of an organization".

Note 4 to entry: Understanding the *infrastructure* (3.5.2) can help to define the context of the organization.

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.27 sustained success: organization success (3.7.3) over a period of time.

Note 1 to entry: Sustained success emphasizes the need for a balance between economic-financial interests of an organization (3.2.1) and those of the social and ecological environment.

Note 2 to entry: Sustained success relates to the interested parties (3.2.3) of an organization, such as customers (3.2.4), owners, people in an organization, providers (3.2.5), bankers, unions, partners or society.

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.28 quality management: management (3.3.3) with regard to quality (3.6.2)

Note 1 to entry: Quality management can include establishing quality policies (3.5.9) and quality objectives (3.7.2), and processes (3.4.1) to achieve these quality objectives through quality planning (3.3.5), quality assurance (3.3.6), quality control (3.3.7), and quality improvement (3.3.8).

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.29 engagement: involvement (3.1.3) in, and contribution to, activities to achieve shared objectives (3.7.1)

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.30 involvement: taking part in an activity, event or situation

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.31 monitoring: determining the status of a system, a process (3.12) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

[ISO/TMB/JTCG Joint technical Coordination Group]

3.32 innovation: new or changed *entity*, realizing or redistributing *value*

Note 1 to entry: Novelty and value are relative to, and determined by the perception of, the *organization* and *interested parties*.

Note 2 to entry: An innovation can be a *product*, *service, process*, model, method etc.

Note 3 to entry: Innovation is an outcome. The word "innovation" sometimes refers to *activities* or *processes* resulting in, or aiming for, innovation. When "innovation" is used in this sense, it should always be used with some form of qualifier, e.g. "innovation activities".

Note 4 to entry: For the purpose of statistical measurement, refer to the Oslo Manual (OECD/Eurostat 2018): New or changed entity' corresponds to 'a new or improved product or process, or combination thereof, that differs significantly from the unit's previous products or processes'. Realising or redistributing value' corresponds to 'and that has been made available to potential users or brought into use by the unit'.

[ISO/CD 50500.2 "Innovation management system – Fundamentals and vocabulary"]

3.33 innovation ecosystem: system (4.1.3) of organizations (4.2.2), people and resources, complementing each other and contributing to a common objective (4.3.3) with regards to innovation (4.1.1)

Note 1 to entry: An innovation ecosystem can include private companies, public authorities, universities, institutes, individual entrepreneurs, investors, researchers as well as funding and infrastructures.

Note 2 to entry: An innovation ecosystem generally includes intangible and qualitative interactions and relationships necessary for its effectiveness (4.7.4).

[ISO/CD 50500.2 "Innovation management system – Fundamentals and vocabulary"]

3.34 strategy: plan to achieve a long-term or overall objective

[ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary]

3.35 transformative/enabling technologies: knowledge intensive, associated with high R&D intensity, rapid innovation cycles, high capital expenditure and high-skilled employment. They enable innovation in process, goods and service innovation throughout the economy and are of systemic relevance. They are multidisciplinary, cutting across many technology areas with a trend towards convergence and integration. KETs have the capacity to improve people's health, safety and security, supporting sustainable development and secure connectivity and communication among systems and individuals.

[European Commission, High-Level Strategy Group on Industrial Technologies, 2009 and 2018]

3.36 management standard: management standard designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse geographical, cultural and social conditions.

[ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2018]

3.37 management system standard (MSS): MSS designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse geographical, cultural and social conditions.

[ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2018]

3.38 documented information
information required to be controlled and maintained by an organization (3.1) and the medium on which it is contained
Note 1 to entry: Documented information can be in any format and media, and from any source.
Note 2 to entry: Documented information can refer to:
— the management system (3.4), including related processes (3.12);
— information created in order for the organization to operate (documentation);
— evidence of results achieved (records).

3.39: RRI product: Research and Innovation project or product of the organization to focus on in the design of the RRI roadmap

4. PRINCIPLES FOR IMPLEMENTING RRI

There is a wide set of papers providing different definitions and principles for RRI. The definition selected for this guideline, i.e. *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*[3], focuses on the social value in product development. This definition has been created considering the EU normative framework, with explicit reference to the Charter of Fundamental Rights of the European Union[4].

Starting from this definition, a set of principles has been developed in literature[5] in order to support the implementation of RRI in different kind of decisional and operative structure and practices. In this guideline, these "management" principles are connected to specific actions lines for RRI implementation along the R&I value chain and product life-cycle, as reported in Table 1.

Table 1: set of principles and actions for RRI implementation

Principles for RRI implementation	Action lines
Reflection & Anticipation	Integrate analysis of ethical, legal and social impacts (ELSI) since the early stages of product development
Inclusiveness	Perform stakeholder engagement to inform all phases of product development
Responsiveness	Integrate monitoring, learning and adaptive mechanisms to address public and social values and normative principles in product development

These principles are further described in the following[6]:

- **Reflection:** scrutinize each activity, commitment and assumption in order to connect them with a moral value system and the good practices of science, taking into account the limits of knowledge and that a particular framing of an issue may not be universally held.
  Reflexivity in RRI context is not to be referred to the moral responsibility of the single researcher or developer, and is not a self-critique of the single professional, but it is intended as an institutional practice. It can also be intended as a public matter and people external to the organization can be part of reflexivity actions. Reflexivity is important also with respect to the other phases of the product value chain or other functions inside the organization (besides the R&D), that could be affected by an R&I action or result.

- **Anticipation:** systematically extrapolate all the plausible scenarios for the application of the R&I results; identify in these scenarios the possible risks, opportunities, uncertainties, critical issues, and draw possible ways to prevent, manage or exploit them.

[3] Von Schomberg, R. (2012). Prospects for Technology Assessment in a Framework of Responsible Research and Innovation. In D. Marc. & B. Richard (Eds.), Technikfolgen abschätzen lehren (pp. 1–19). VS Verlag für Sozialwissenschaften. https://doi.org/10.1007/978-3-531-93468-6_2

[4] See https://www.europarl.europa.eu/charter/pdf/text_en.pdf

[5] Lubberink, R., Blok, V., van Ophem, J., & Omta, O. (2017). Lessons for Responsible Innovation in the Business Context: A Systematic Literature Review of Responsible, Social and Sustainable Innovation Practices. Sustainability, 9(5), 721. https://doi.org/10.3390/su9050721

[6] Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. Research Policy, 42(9), 1568–1580. https://doi.org/10.1016/j.respol.2013.05.008

Anticipation isn't only intended to prevent undesirable events, but also to shape desirable futures and organize activities and resources towards them. When describing desirable futures, anticipation should be realistic and avoid to overestimate the benefits of the innovation.

- **Inclusiveness:** introduce participatory approaches in the R&I processes from the very early stages, in order to engage people interested with the innovation process or results. Inclusion is referred to the engagement of both internal and external stakeholders. Inclusion is also connected to the other dimensions of RRI, because the reflexivity, anticipation and responsiveness can be improved by a broad participation of different stakeholders.

- **Responsiveness:** change the direction of the innovation process to answer to stakeholder and public indications, needs, and values or to react to changing circumstances. It could be necessary also to adjust innovation actions when recognizing insufficiency of knowledge and control, or in response to new knowledge, perspectives or regulatory requirements. The entire R&I processes should be shaped to be as responsive as possible.

The Box includes a collection of scope, principles and values of some ISO management systems, providing a useful reference for the implementation of the RRI approach described above.

Scope, principles and values of ISO standards on social responsibility, risk management, quality and innovation management

ISO 26000 (Social Responsibility)	**ISO31000 (Risk Management)**	**ISO 9001 (Quality Management)**	**ISO 56000 (Innovation Management)**
Guidance to integrate, implement and promote socially responsible behavior throughout the organization and, through its policies and practices, within its sphere of influence.	Guidance on a common approach to managing any type of risk throughout the life of the organization.	Requirements to demonstrate ability of the organization to consistently provide products and services that meet customer needs (conformity) and applicable statutory and regulatory requirements	Describes the fundamental concepts, principles, and vocabulary of innovation management
➢ Accountability ➢ Transparency ➢ Ethical behavior ➢ Respect for stakeholder interests ➢ Respect of the rule of law ➢ Respect for international norms of behavior ➢ Respect for human rights	A risk management framework: ➢ Integrated in all organizational activities ➢ Structured and comprehensive ➢ Customized to the organization's external and internal context ➢ Inclusive, considering knowledge, views and perceptions of stakeholders ➢ Dynamic and adaptable ➢ Based on best available information ➢ Taking into account human and cultural factors ➢ Based on continual improvement, through learning and experience.	➢ Customer focus ➢ Ensuring leadership on the management system ➢ Engagement of people ➢ Process approach, to operate as an integrated and complete system. ➢ Based on continuous improvement to meet customer requirements and enhance customer satisfaction. ➢ Evidence- based-decision making ➢ Relationship management	➢ Realization of value, as the ultimate objective, for organizations to engage in innovation activities ➢ Future focus leader, driven by curiosity and courage, challenge the status quo ➢ Strategic direction for innovation ➢ Culture ➢ Exploiting insights: using a diverse range of internal and external sources ➢ Managing uncertainty ➢ Adaptability ➢ System approach

5. METHODOLOGICAL APPROACH

Based on the principles described in clause 4, the methodological approach to the different steps of the process leading to the implementation of the RRI in the industrial practice are synthetically indicated in the Figure 1 and explained in detail in clause 6. The final goal is the definition of a RRI Roadmap setting a strategy, indicating a vision and specific actions for RRI implementation in product development. The structure and visualization of the roadmap is provided in Figure 2. The roadmap design includes definition of the following elements:

- The Research and Innovation product (s) on which to focus the RRI roadmap
- The vision for RRI implementation in the product development
- The time-scale for the implementation of the RRI roadmap
- The drivers and challenges, risks and barriers to achieve the vision, based on the assessment of the present status
- The RRI actions to pursue, as possible path(s) between present and future to reach the vision
- The resources and process owners needed, their feasibility and consistency with the overall organization strategy and the innovation eco-system

The list of the methodological steps for the roadmap design is reported in Table 2, including indication of the different phases of development of the roadmap structure, leading to the roadmap design.

The process proposed in this guideline is circular: top management commitment prompt and facilitate the process of roadmap design and as well is informed by it.

The approach has been tested in practice by implementing it with eight pilots referring to industrial research projects related to transformative technologies (described in Prisma deliverable 5.2, part B). In particular nanotechnologies, biotechnologies, the Internet of Things and autonomous vehicles. This exercise helped to refine, and deepen the different issues, steps and actions. The outcomes have been translated into the framework described below.

Table 2: List of methodological steps for the roadmap design

	STEP	GOAL	ROADMAP PREPARATION
	Section 6.2: TOP MANAGEMENT COMMITTMENT AND LEADERSHIP	Ensure endorsement of the organization toward RRI values and approach	Setting of the initial RRI vision, and selection of RRI product candidates
	6.3: CONTEXT ANALYSIS	Analyze the organization, the R&I product(s) and technologies to focus on; Identify ethical, social and legal impacts of the product and stakeholders of the product innovation eco-system	Compilation of the 4th line of the roadmap (R&I tech and products)
	6.4: MATERIALITY	Identify and prioritize: drivers and challenges for RRI; risks and barriers to overcome; stakeholders to work with; significant RRI actions to pursue	Compilation of 1st and 2nd lines of the roadmap; refinement of the vision; first version of the RRI actions (3rd line)
	6.5: EXPERIMENT & ENGAGE	Perform exploratory/pilot RRI actions, engaging with stakeholders to inform the RRI roadmap	Review of the overall roadmap with stakeholders
	6.6: VALIDATE	Evaluate impact of the roadmap on both the product development and the organization (Key Performance Indicators)	Review of RRI actions, in view of their technical, ethical, social, environmental, and economic impacts
	6.7: ROADMAP DESIGN	Consolidate and visualize the long-term RRI strategy, covering all the R&I value chain (time to market) and product life-cycle.	FINAL ROADMAP

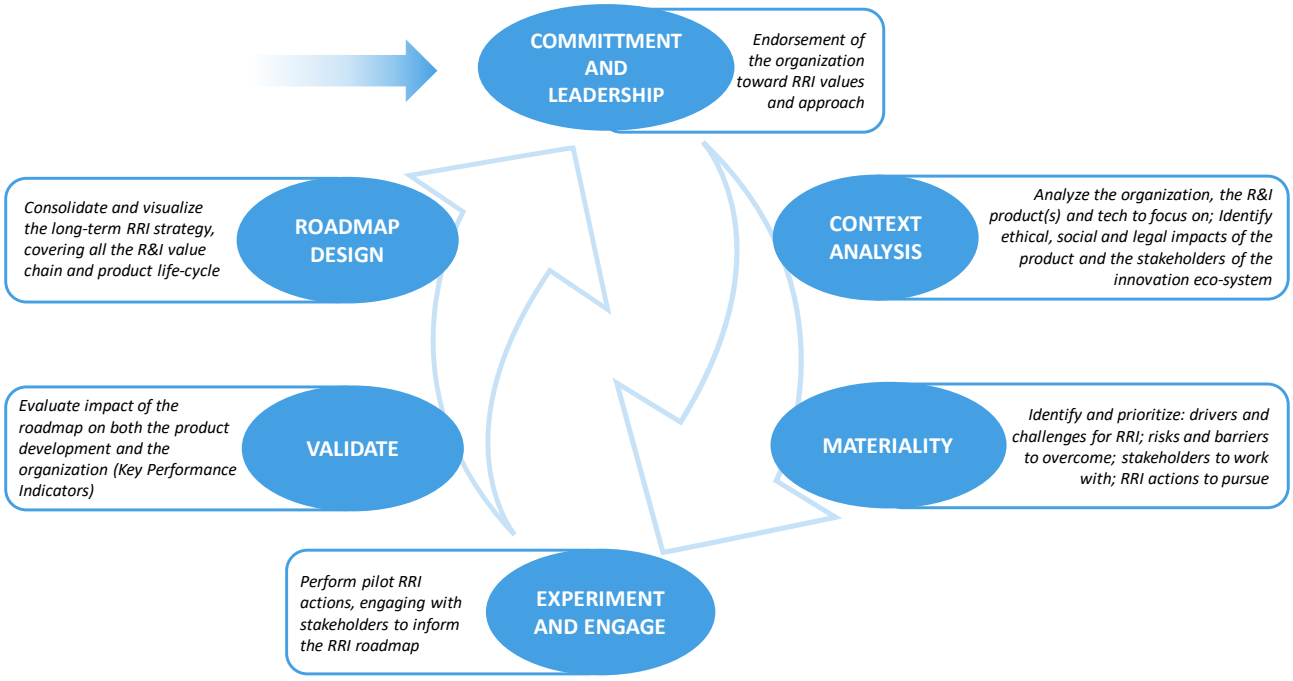


Figure 1: Overall approach and steps leading to the definition of the RRI roadmap

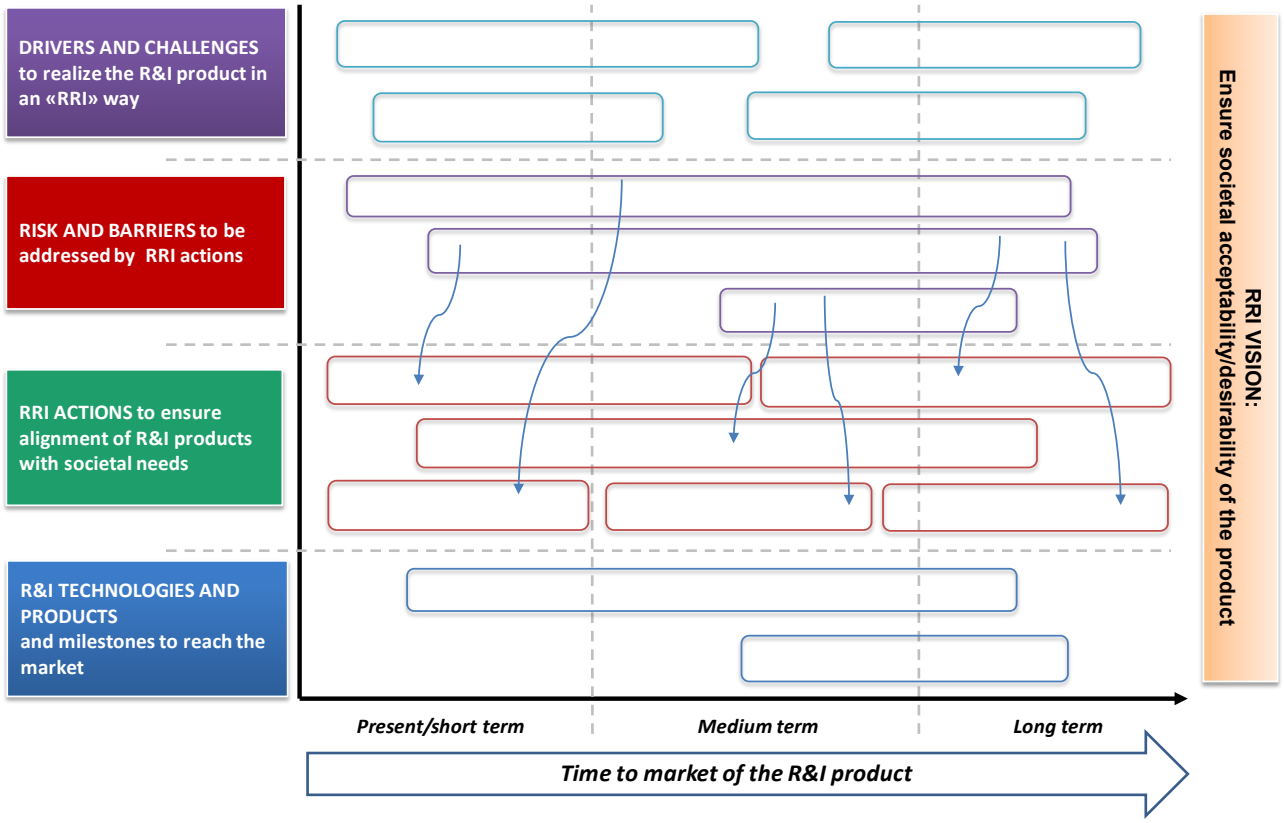


Figure 2: Visualization of the RRI Roadmap

6. FRAMEWORK FOR DEVELOPING THE RRI ROADMAP

6.1 General

In developing the framework from clause 6.2 to 6.7, the high-level structure (HLS), i.e. identical core text, common terms and core definitions for all ISO management system standards, as well as other relevant management standards, have been considered.

NOTE for what concern ISO management system standards ISO 9001 series and ISO/FDIS 56000 series were considered. As far as management standards are concerned ISO 26000 and ISO 31000 were taken as references.

It is envisaged that a third-party organization is engaged by the organization, in order to advise and oversee the implementation of these guidelines. The third-party organization should have a specific expertise on RRI related issues (e.g. ethical, social, legal impacts analysis).

6.2 Top Management commitment and leadership

A pre-requisite for RRI implementation is top management commitment. This commitment is necessary but not sufficient to achieve RRI intended outcomes, as the top-down approach should be integrated with a bottom-up approach, involving other roles providing leadership.

Top management shall demonstrate leadership and commitment with respect to the RRI by:

- ensuring that the RRI roadmap, related actions, objectives and vision are established and are compatible with the values and identity and stakeholders the organization is referring to
- identifying and sustaining the motivation for the company to engage with RRI
- ensuring that RRI principles are integrated into the organization's management systems and governance to ensure that the RRI achieves its intended outcome(s)
- ensuring that the resources needed for both the roadmap design and its future implementation are available (also on the long term)
- communicating the importance of effective RRI, supporting the application of the guidance provided in this document
- supporting other relevant roles for RRI implementation, for example supporting RRI promoters

This process will lead to an initial formulation of the vision for the RRI roadmap and a selection of possible Research and Innovation projects or products to focus on in the design of the RRI roadmap ("RRI product")

6.3 Context analysis

RRI is connected to a broad spectrum of factors related to the type and management policies of a company, the technology and products it works on, the sectors and markets, the pertinent regulatory frameworks and stakeholders involved. For an effective and efficient RRI uptake, it is essential to identify strategies and practices that fit with the realities and constraints in which the organization operate.

The following elements are identified, at least in draft form:

1. **The ethical, legal and societal impacts, and as well as the technical, strategic, organizational, economic impacts concerning the RRI product**. This analysis is expected to influence the selection of all the roadmap elements and the setting of the vision, and will feed into clause 6.2 (materiality)
2. **The specific technologies and products**, and related R&I projects, on which to focus the RRI roadmap design ("RRI product")
3. **The development stages of the RRI product**, from the start of the analysis to the expected time to market of the product. (4th line of the roadmap)
4. **The stakeholders interested/involved in the development of the RRI product** throughout the innovation eco-system, including an initial understanding of their needs and perspectives (based on desk analysis)

Note: If the RRI roadmap is meant to cover the whole life cycle of the product, the roadmap time frame could include the product end of life.

Internal and external issues of the organization and of the specific RRI product concerned with the roadmap design contribute to shape the analysis. For what concerns the **internal issues**, it is essential to consider the identity of the organization and to take into account:

a) mission: the organization's purpose for existing

b) vision: aspiration of what an organization would like to become

c) values: principles and/or thinking patterns intended to play a role in shaping the organization's culture and to determine what is important to the organization, in support of the mission and vision

d) culture: beliefs, history, ethics, observed behavior and attitudes that are interrelated with the identity of the organization

f) The management models used in research and innovation

e) the formal and informal policies and procedures implemented by the organization for social responsibility, and quality and risk management

f) The impact of research and innovation on the core business of the organization

g) The characteristics of the RRI product, in terms of the type of technology and innovation, the expected applications, the technology readiness level (TRL) and time to market, the expected R&I steps to develop the final RRI product,

Notes: part of these points is derived from [ISO 9004:2018, 6]; The specific type of technology can be classified in terms of: front runner, directly product oriented, incremental or radical innovation.

For a proper understanding of the **external issues**, at least the following aspects should be considered:

h) the market segments and structure, in terms of opportunities and barriers for exploitation and deployment of the RRI product within the innovation eco-system and in the market

i) the normative and regulatory regimes concerned with the RRI product

l) the public and stakeholder awareness on the technology and product developed

m) the type of information that could or couldn't be disclosed to stakeholders (IPR and trade secrets)

n) what stakeholders (and procedures) are usually considered within the innovation ecosystem

For the analysis of internal and external issues, tools such as SWOT (analysis of strength, weaknesses, opportunities, and threats) and PESTLE (analysis of political, economic, socio-cultural and technological, legal and environmental factors) can be used.

Based on the identification and analysis of internal and external issues, the organization shall map relevant stakeholders and understand their needs and expectations, by taking into account those parties that are relevant for RRI implementation and in particular linked to the organization innovation ecosystem. Consideration of the needs and expectations of interested parties can help the organization:

a) to achieve objectives effectively and efficiently

b) to eliminate conflicting responsibilities and relationships

c) to harmonize and optimize practices

d) to create consistency

e) to improve communication

f) to facilitate training, learning and personal development

h) to manage risks and opportunities to its brand or reputation

i) to acquire and share knowledge

This activity can be considered as a context analysis.

Model of a questionnaire to compile information for the context analysis

Facts and figure:
- Field of activity
- Company ownership
- Size of the organisation
- Date of establishment
- Member of trade organisation

Type of organization:
- Organisational structure
- Business model
- Organisational culture
- Gender balance and gender policy (focus on R&I)

R&D and Innovation function:
- Size
- Relevance for the organization
- Type of research activity
- Characteristics of personnel: age, education, sex, home country, race
- role of the R&I compared to the CSR strategy of the organization
- Innovation management model

Experience with CSR and RRI:
- CSR, sustainability, risk and quality strategies
- Responsibilities within the organization
- Experience on stakeholder engagement

Case description:
- Project description
- Technologies
- Regulatory regimes
- Type of R&I activities
- Type of business
- Time to market

6.4 Materiality analysis

A key aspect of RRI is anticipation. Identify materiality aspects of the RRI product and the organization early on in the R&I value chain is essential to anticipate impacts, and thus have time to change and adapt the process to ensure creation of value (e.g. maximize positive impacts and minimize negative ones).
The term materiality brings two concepts into play:
- understanding what (contents) is **relevant** in terms of RRI with respect to the context in which the RRI product and the organization finds itself and operates
- understanding how much the relevant content is **significant**

The goals of this phase are thus the following:

1. Identify **relevant ethical, social and legal impacts** of the RRI product, and describe them in terms of **drivers** (creation of value, positive impacts), and **challenges** (of the organization in achieving the impacts)

2. **Identify the risks and barriers** (uncertainties) to address in order to achieve the impacts. Scientific, technical, strategical, organizational, economic, ethical and social aspects should be considered in determining risks and barriers
3. **Select stakeholders within the innovation eco-system** of the RRI product to engage with
4. **Select significant RRI actions** that can contribute to achieve impacts and as well address risks and barriers
5. **Set an initial vision of the roadmap,** addressing drivers and challenges

A first complete version of the roadmap is prepared based on these elements. Examples of specific RRI actions are reported in the appendix.

Note: In the elaboration of the roadmap, the materiality analysis needs to be linked to the technology readiness level of the product, and the time to market (1st line of the roadmap). It has to be defined when a specific issue will arise along the product development phase, and thus what actions to be done when.

The goal of this phase is to identify what impacts and what RRI actions are relevant to decisions and activities of the organizations, and develop a set of criteria that help decide which of them are most significant.

This means determining which issues are more important to the organization in terms of priority, e.g. the extent of the impact on stakeholders, society or sustainable development, consequences arising from a non-management of that very issue, perceptions and expectations of stakeholders, and the overall impact on the product development and the organization.

A particular attention should be given to the “agents” of the innovation eco-system, whose actions and decisions can affect the organization and on which the organization activities may have an effect and/or an impact (positive and/or negative).

Additionally, it seems clear how much an approach to the determination of materiality should be based on:
a) a strong link to organizational governance and to the determinants of the value chain and of the creation of economic value (value drivers)
b) a set of clear and transparent criteria that support the organization in deciding what is "material"
c) an integration with the governance itself

The understanding of the 'context' and the sphere of influence of the organization is critical in this exercise, as it implies the ability to reflect with a broad vision on the impact that the actions and decisions of the organization have, or might have, within the organization itself, and also on stakeholders and on RRI (and vice versa).

As acknowledged by the experience in the social responsibility field (e.g. ISO 26000), the identification of material issues to address is not a simple exercise. While the methods developed from the perspective of economic and financial materiality capture only those relevant areas that impact performance or risks in the short term, from the perspective of RRI the time frame shall consider not only short-term impacts and effects, but also ones in the medium to long term, including both tangible and intangible aspects.

It is important that the views of the stakeholders are always considered and appropriately integrated into the reflections internal to the organization. The stakeholder’s analysis involves the identification of relevant groups, organizations and people, their perspectives and relevance. Having this in mind, stakeholders can then be mapped, using one of the many tools available for this purpose. An example of stakeholder analysis is presented in the box. Examples of tools for this purpose are the materiality matrix and the interest/influence grid (see appendix).
The materiality analysis started in this phase, is then complemented by the other phases. Clause 6.5 require the organization to perform inclusiveness actions (e.g. stakeholder engagement), a fundamental element in

determining significance, both to broaden perspectives on issues and impacts, and to capture inputs on prospects and emerging needs that, at the moment, do not seem particularly critical but could become such in the future.
The validation phase (clause 6.6.) helps the organization to identify a set of criteria to evaluate the impact of the identified RRI actions on product development and the organization and thus complete the materiality analysis.

An example of questions to deal in a materiality analysis, are the safety and privacy issues related to operations of autonomous vehicle devices. What are the safety concerns (both actual and perceived by stakeholders) related to the different conditions of work of the device? How to manage the data the device could or have to collect during its operations? Is the collection of these data critical from a social, ethical and legal point of view? What could be the ethical issues related to autonomous decisions that these vehicles might have to take during their operations? All these aspects are relevant, but depending from the specific device (e.g. autonomous cars or drones), the technology (e.g. the type of data collected, the way these are managed by the device, etc.), the use scenarios (e.g. use of the device in buildings, cities, farms, etc.) and the stakeholders concerned, the definition of significant issues for the specific products (materiality) could completely change.

Example of an exercise for stakeholder analysis in the innovation eco-system

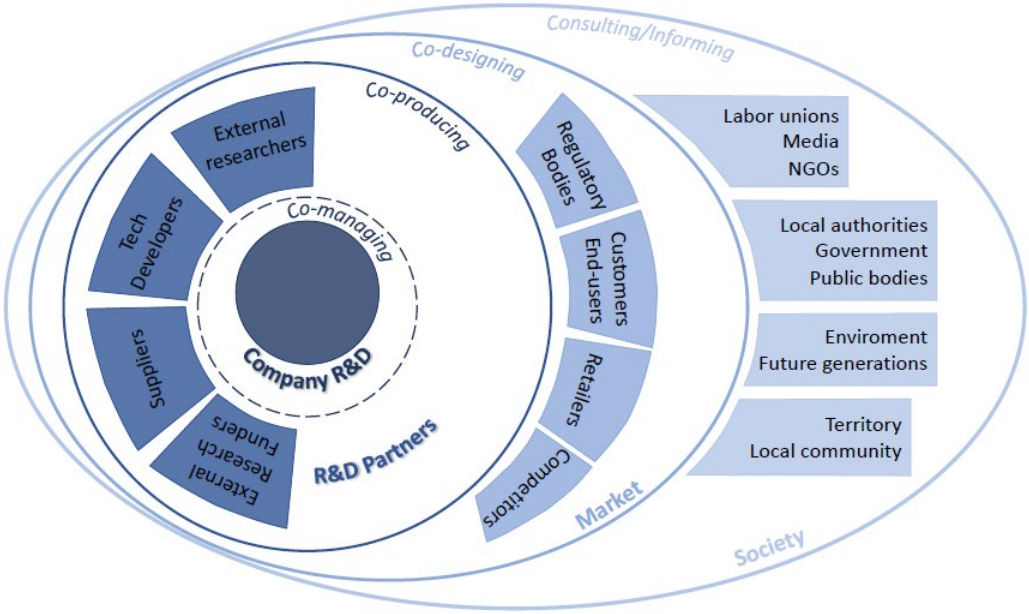
Stakeholder analysis consists in identifying all the relevant stakeholders and their interests connected to a specific topic. This can be done by following four main steps:

- Identify: relevant groups, organizations, and people
- Analyze: the contribution that each stakeholder can provide, their legitimacy or willingness to be engaged, how much influence does each stakeholder have (and who/what is able to influence) or how could they delegitimize the process if not involved
- Map: the core part of the "mapping exercise" consists in putting together the information about the stakeholders in a graphical way in order to visualize which stakeholders is must useful to engage with, based on selected criteria (see the appendix to have some practical examples)
- Prioritizing: ranking stakeholder relevance, in order to understand who has to be engaged from the beginning or more intensively, being clear in establishing why each stakeholder has been selected (this is important to save time and also to interact with them in the right moment with a proper motivation)

It is important to implement RRI with an innovation ecosystem approach. The ecosystem has to be identified and built (or strengthened, if already on place). Some useful actions could be:

- Identify the role of all the stakeholders sharing benefits and risks of innovation
- Select instruments enabling interaction of these actors at all levels
- Establish common (RRI compliant) standards/processes/procedures/certifications within the innovation ecosystem

The following figure is an example of mapping of stakeholders in the innovation eco-system, including indication of their potential role in product development



6.5 Experiment and engage

Stakeholder engagement is one of the pillars of RRI, and it is as well essential in order to validate the materiality analysis and the design of the roadmap. On the basis of the previous steps, it is possible to identify one or few RRI pilot actions that the organization should perform in order to ascertain the appropriateness and the feasibility of the RRI roadmap. Thus, in this phase the following aspects are addressed:

1. **At least one inclusiveness action is performed,** involving stakeholders within the innovation eco-system in discussing and analyzing key ethical and social impacts of the project and in reviewing the draft roadmap
2. **Additional RRI actions are performed,** as a way to practice and pilot activities planned in the roadmap

In the selection of the actions, is suggested to make a step further compared to usual organization practices (out of the "comfort zone" of the organization, in terms of issues discussed, information provided, stakeholders engaged, methods used, etc.).

There are plenty of methods available to perform stakeholder engagement, and different goals that could be pursued (e.g. inform, consult, involve and collaborate).

The main objective in this phase is to create a dialogue with stakeholders of the innovation eco-system (as selected in the materiality analysis) to discuss their views and perspectives on the RRI product and its ethical, legal and social impacts, and on the specific elements included in the roadmap.
Examples of suitable methods include focus groups, plenary sessions, multi-stakeholder workshops, world-café, and fish-bowl exercises. A more detailed list of the methods is provided in the appendix. Recommendations to perform stakeholder engagement are provided in the box.

Initiatives aiming only at informing on product development, observing and studying people's behaviour, testing of a product should be avoided.

The outcome of this phase is a complete materiality analysis, in terms of significant ethical, social and legal impacts to address, and stakeholders of the innovation eco-system and a consolidated version of the roadmap.

Practical recommendations for stakeholder engagement:

- Learn from past and on-going engagements. Make a reflection on the positive aspects and possibilities for improvement
- Identify and communicate in advance to all stakeholders the goals and expected outcomes
- Ensure most representative stakeholders along the value and supply chain are engaged. If appropriate, consider different type of engagement activities for the different stakeholders (e.g. a focus group with research and business partners, a workshop with authorities, a multi-stakeholder initiative to involve users, together with research and business partners)
- Be social. Social medias provide a perfect opportunity to identify and reach lesser-known stakeholders groups
- Select the engagement method, taking into account the number of stakeholders to be involved, their level of interest and knowledge, their willingness to participate and the kind of contribution they could provide (as identified in the materiality analysis)
- Look for diversity of participants, in terms of experience and skills, geography, as well as gender and age
- Set clear rules for engaging stakeholders (e.g. confidentiality, decision making process)
- Identify motivation for stakeholders to contribute, if appropriate consider rewarding mechanism for them
- Carefully design/select: the information to be provided in advance and during the event; the structure of the event; moderators/facilitators; the ways for reporting outcomes; feedback mechanism and/or evaluation methodology; the tools for communication and dissemination.
- Look for interactive ways of engaging stakeholders, consider to assign active roles to the participants
- Consider stakeholder expectations, ensure an equal possibility to all, avoid polarization and mitigate the possible tensions, stick the discussion to the agenda and the objectives and avoid off-topics
- Provide documented information on the engagement activities. Include at least: a summary of stakeholder concerns, expectations and perceptions; a summary of key discussions and interventions; and outputs (e.g. queries, proposals, recommendations, agreed decisions and actions)
- Ensure follow up of the event (e.g. share presentations, distribute a report of the event, give the opportunity to all participants to comment, communicate decision taken based on the event results, organize follow up initiatives, etc.)
- Keep in mind that stakeholder engagement is a process, not an event or a one-off exercise

6.6 Validation

The success of RRI up-take is strongly context-dependent and is affected by several factors, as underlined in the context analysis clause (e.g. company size, complexity of the organization, features of the technology, the level of innovation and the associated risks). RRI actions could have both tangible and intangible impacts, spanning from long-term strategic factors at the company level (e.g. company reputation) to short-term factors in product development (e.g. alignment with user needs and stakeholder values).

In this phase the organization evaluate and validate the added value of the roadmap in terms of its impact on the product development and the company, based on selected criteria. This process is needed both to evaluate the feasibility of the roadmap for the organization, and, if necessary, to refine it.

The definition of criteria is also helpful to provide documented information on the roadmap, that could be controlled and maintained by the organization during the uptake of the roadmap actions. Thus, in this phase the following aspects are address:

1. **Identify what needs to be measured and monitored**, selecting criteria to perform evaluation of impacts of RRI actions
2. **Select the methods for measuring, monitoring, and evaluating the impacts** of the roadmap on the RRI product and the organization
3. **Evaluate (at least qualitative) the impacts of the RRI actions** defined in the roadmap, focusing on the added values both tangible and intangible, based on the selected criteria
4. Explore whether and to what extent the roadmap could be embedded in the usual innovation, risk, quality, social responsibility policies of the organization. This includes identification of Key Performance Indicators to measure impact of RRI actions on the organization

Relevant examples are provided in the appendix with respect to: a set of criteria and a qualitative methodology for the evaluation of the impact of the RRI roadmap on product development (points 1,2,3); quantitative Key Performance Indicators to evaluate impact of RRI on the organization (point 4).

The organization should as well determine resources and processes needed to operationalize the actions indicated in the roadmap, namely:

1) People
2) Time
3) Knowledge
4) Finance
5) Infrastructures, i.e. tangible and intangible assets and technological infrastructures

The role and contribution of relevant “agents” (i.e. relevant interested parties within the innovation ecosystem) to implement the roadmap should also be considered.

The organization shall retain appropriate documented information as evidence of the results.

This step might lead to changes in the planned RRI actions, to ensure these are aligned with the overall strategy of the organization and the resources available. This will lead to the final version of the RRI roadmap (6.7).

6.7 Roadmap design

Based on the outcomes of the above-mentioned steps, a RRI roadmap is designed to guide an organization to put in practice the key RRI implementation principles already indicated in clause 4:

1. Anticipation & Reflection: Integrate analysis of ethical, legal and social impacts since the early stages of product development
2. Inclusiveness: Perform stakeholder engagement to inform all phases of product development
3. Responsiveness: Integrate monitoring, learning and adaptive mechanisms to address public and social values and normative principles in product development

The RRI roadmap of the organization should include at least one specific action for each of the above three key principles. Examples of specific actions are reported in the appendix.

The PRISMA RRI roadmap is built taking advantage of the experience made with the industrial pilots mentioned above, to cope with the RRI principles and tools in the context of rapid (and possibly disruptive)

scientific and technological developments associated with transformative technologies. Its guidelines and actions, however, have a general validity. Its design adapts the architecture of the generic IPRM to decision-making on RRI strategies as shown in the figure below, already anticipated in clause 5.

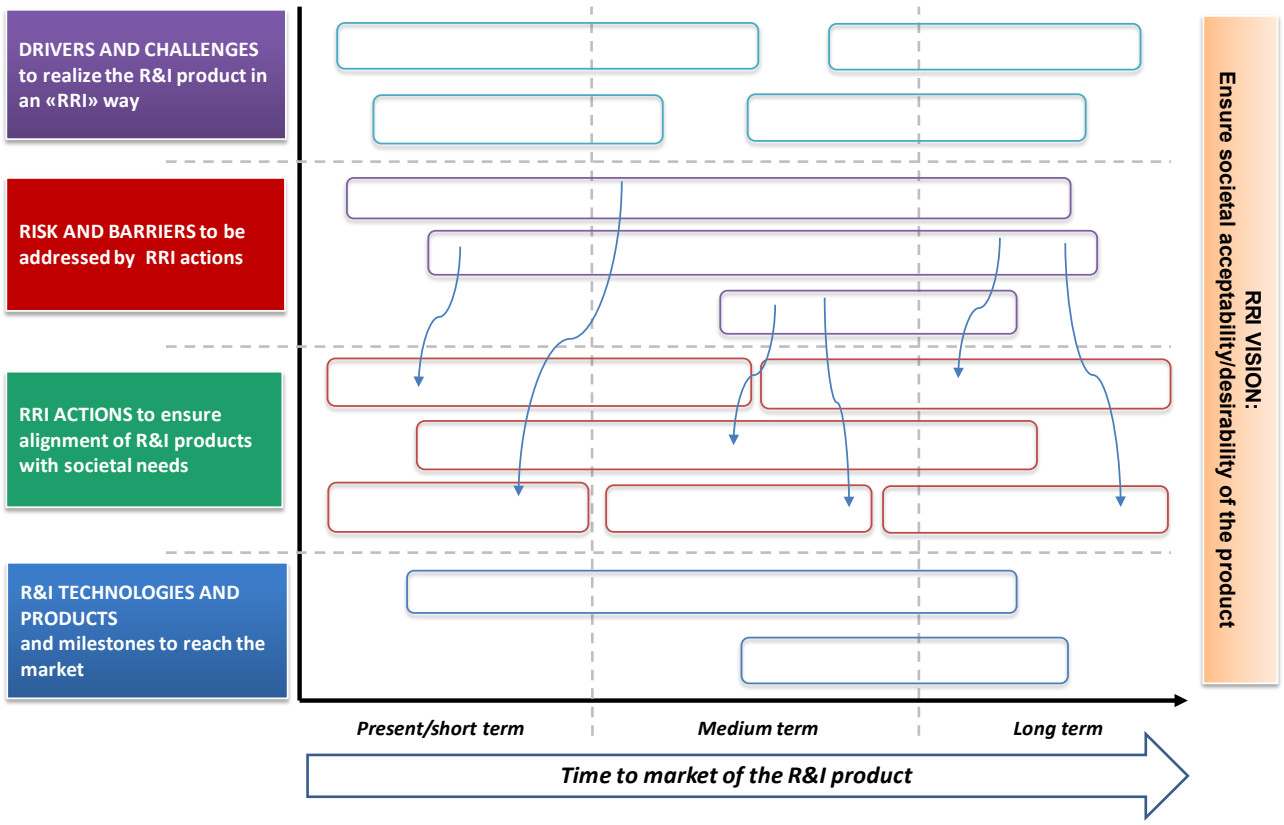


Figure 3: PRISMARRI roadmap template

As shown in the template (Figure 3), the PRISMA RRI roadmap has four areas of action and its design starts with the definition of the desired outcome of RRI implementation (vision) (6.2). That means:

-1st line (compilation starts at 6.3): the definition of the drivers and the challenges, based on consideration of the significant ethical, social and legal impacts, and strategic, organizational and economic issues at stake, for both the organization and the specific RRI product

-2nd (compilation start at 6.4): the identification of the risks and barriers addresses by the RRI actions

- 3rd (compilation starts at 6.4): identification of an action plan to implement RRI all along the steps for product development, core part of the roadmap

-4th (compilation starts at 6.3): identification of the innovative technologies that enable to address the objectives of the research and innovation (RRI product)

The X-axis of the RRI roadmap shows the expected duration of the research and product development, until the entry into the market (time to market). It might include also the use and end of life of the product, if a life cycle perspective is considered in the definition of the roadmap (in this case time to market is replaced by life cycle).

The market demand plays an important role on the technology-based solutions under investigation and the societal implications may affect the technological developments.

Stakeholder involvement plays an important role at all levels.

The construction of the proposed roadmap is a flexible and adaptable process using a "toolbox" with different modules and consists of several levels. The starting point, is the long term RRI vision. All the intermediate targets should be designed in relation to long term RRI targets and include the RRI anticipatory, reflective, deliberative and responsive principles (clause 4).

Important elements for the design of the roadmap and its implementation are also the RRI pilot actions that the organization should perform in order to ascertain its feasibility (6.5) and the evaluation and validation of the added value given by the roadmap on product development, as well in terms of resources to put actions into practice (6.6).

Besides the graphical representation in the Figure 3, document information will be provided describing in more detail the RRI roadmap policy. An example of contents is indicated in the box.

Template of documented information to be provided on the RRI roadmap

Case description

- The Company
- RRI commitment
  - Functions of the organization endorsing the roadmap
  - Motivation to implement the roadmap
- Context
  - Size and ownership of the organization
  - Date of establishment, country
  - RRI product selected
  - Technologies
  - Regulatory regimes relevant for the RRI product
  - Type of R&I activities
  - Type of business
  - Time to Market
  - CSR policies
  - Gender balance and gender policy in R&D/R&I
  - RRI Maturity Level
- Materiality & experimentation
  - Significant stakeholders
  - Significant ethical, social and legal impacts
- Validation aspects
  - Criteria to evaluate impact of RRI actions on the RRI product
  - Key Performance Indicators to monitor RRI aspects within the organization

RRI Roadmap

- RRI vision
- R&I Technologies and products
- Drivers and challenges for RRI
- Risks and barriers to be addressed by RRI actions
- RRI actions
- Roadmap design

APPENDIX

RRI Actions

In Table 3, Table 4 and Table 5 are indicated examples of main actions to implement RRI in product development at company level, with reference to expected benefits, the R&I value chain, the corporate functions the stakeholders involved, and the term of investment. These actions are derived from the experience of PRISMA, and literature review (in particular outcomes of other initiatives dealing with RRI implementation in companies).

Table 3: Key action on REFLECTION & ANTICIPATION:
Integrate analysis of ethical, legal and social impacts (ELSI) throughout all stages of product development

Actions	Benefits	R&I Value chain phase	Corporate functions involved	Stakeholders involved	Invest-ment Term
Including RRI principles in company's mission and vision, including reflection on Creating Shared Value	-Improve product quality, desirability and acceptability - Improve product sustainability, safety and reliability -Address uncertainties, prevent and mitigate risks - Motivate workers	All	Management	R&I partners	Short
Ethical analysis, through foresight, scenario analysis, social phenomena and trends evaluation, etc.		Basic and applied research, engineering and testing	Management, R&D	R&I partners end users, policy makers	Short, Medium
Design for values, stakeholder and value inventory/scenarios (values hierarchy, conflicting values, etc.)			R&D	R&I partners, suppliers, end-users	Short, Medium
Internal meetings with R&D personnel to reflect on ethical issues			R&D	Internal to the company	Short
Advice from (independent and external) experts on ELSI, on a need basis			R&D, CSR, Legal	Internal to the company	Short
Develop and introduce ethical frameworks, code of conducts		All	Management, legal, R&D, CSR, quality	Internal to the company	Medium
Implement Life Cycle Assessment (LCA) and Social-LCA		Applied research, engineering and testing	Management, R&D, Quality, CSR	Suppliers	Long
Re-evaluate expected impacts prior to the market launch		Go to market	R&D, Quality, CSR	R&I partners, End-users	Short

Table 4: Key action on INCLUSIVENESS:
Perform stakeholder engagement to inform all phases of product development

Actions	Benefits	R&I Value chain phase	Corporate functions involved	Stakeholders involved	Invest-ment Term
Set and implement a communication and dialogue strategy on ELSI	-Strengthen relations and trust with all stakeholders, networks building - Reconcile opposing views and bridging opposing values - New values creation - Anticipate potential regulatory change - Product quality, desirability and acceptability	Engineering and testing, Go to market	R&D, CSR, Marketing	All	Long
Work with business and social actors sharing values and create positive ethical networks		All	CSR	All	Medium
Co-design product through dialogue with policy actors and authorities and normative bodies (EU, regional and local)		Applied research, engineering and testing	R&D, Quality, Legal	Policy makers, regulators	Short
Organize public dialogues, build/use public platforms for expressing needs and concerns			R&D, CSR	End users and consumers	Medium
Living labs and social experimentation, participatory methods			CSR, R&D	End users and consumers	Short, Medium
Build user-based communities of practice			R&D, CSR	End users and consumers	Medium
Promote initiatives for social inclusion, provide consumers an official role in the innovation process		All	CSR	End users, policy makers	Medium
Capacity building with vulnerable actors in the value chain		Engineering and testing, Go to market		End users	Medium

Table 5: Key action on RESPONSIVENESS:
Integrate monitoring, learning and adaptive mechanisms to address public and social values and normative principles in product development

Actions	Benefits	R&I Value chain phase	Corporate functions involved	Stakeholders involved	Invest-ment Term
User-centered design, user innovation, flexible and adaptive design, co-creation approaches	- Create value, increase the social value/impact of R&D - Build corporate image and reputation -Compliance with qualified norms and standards - Facilitate the access to financial support	Applied research, Engineering and testing	R&D, Management, Legal, Marketing	R&I partners, supply chain suppliers, end-users and consumers	Long
Screen suppliers for positive practices, share social and environmental issues to be addressed with suppliers			CSR, Management	Supply chain suppliers	Medium
Put in place procedures for investigating reports of concerns or misconduct (e.g. whistleblowing)			All	Internal R&D, R&I partners, supply chain suppliers, end-users and consumers	Medium
Ensure non-discriminatory recruitment processes			HR, CSR	Internal to the company	Short
Adaptive risk management			Management, R&D, quality	Internal to the company	Medium
Embedded ethicists in the R&I process		All	CSR, R&D	Internal to the company	Medium
Establishment of an ethical, social and legal monitoring board		All	R&D, Management	R&I partner, supplier, policy makers, end-users	Long
Include ELSI criteria in internal procedures for R&D project quality monitoring (check-list, guidance)		Applied research, Engineering and testing	R&D, Management	Internal to the company	Short
Ensure ethical management of research data and FAIR data management[7]		R&I, CSR	R&I, CSR	R&I partners, internal to the company	Medium
Perform regular ethical review and get ethical certification (by independent bodies)		Engineering and testing, Go to market	CSR, quality	Certification bodies,	Long

[7] FAIR data principles: Findable, Accessible, Interoperable, re-usable- See https://www.go-fair.org/fair-principles/

				regulators and authorities	
Social accountability and quality certification at company and supply chain level			CSR, quality	Certification bodies, regulators and authorities, investors	Long
Post-marketing monitoring of ELSI impacts		Go to market	R&D, quality	Regulators and authorities	Long
Explicitly include ELSI of R&D and Innovation products in the CSR/sustainability reporting			CSR, Marketing	All	Long
Support and invest in sustainable supply chains		Go to market	Management	Suppliers	Long
Select funding mechanisms based on ethics/responsibility requirements		All	R&D, management	Funding bodies, investors	Short

Table 6: Focus on the embedded ethicist approach

Description	Opportunities and barriers
Embedded ethicists aim at what has been described as "co-operative co-shaping" of technology. It can be understood as involving iterations of the following steps, as put forward by Gorp and S. van der Molen: • Gathering of data about the project to help identify ethical issues • Reflecting on these issues and searching for relevant ideas in literature • Preparing the discussions on the ethical issues and decisions that would have to be made • Having a discussion with the team or some researchers and taking a decision • Reporting about the ethical issues and decisions made	This approach has the potential downside that it may be yet more demanding upon the technologists' time, and the potential advantage that it facilitates more dynamic and deeper reflection on the issues that are raised. On the positive side, the interaction with the technologists on particular problems is a very effective way of accelerating understanding of the issues within the company, and willingness to engage frequently with ethics is a good measure of the seriousness of the company with respect to ethics. The fact that this is time-consuming for ethicists is outweighed by the accellerated understanding they get of the technology issues.

Table 7: Selection of tools to support implementation of RRI actions included in Table 3, Table 4 and Table 5
(based on data in the PRISMA RRI toolkit - www.rri-prisma.eu/toolkit)

Name	AR*	IN*	RE*	Organization
Matter Principles for Responsible Innovation	✔			MATTER (UK)
Responsible innovation- quick-scan assessment matrix	✔	✔		Karim project (EU)
B-Impact: social and environmental impact benchmarking	✔	✔	✔	B Corp.org
Gendered innovations in research and innovation		✔		European Commission
Stakeholder maps		✔		Transnational Network for Social Innovation Incubation (EU)
Stakeholder engagement: Rethinking your strategy for stakeholder engagement	✔	✔	✔	BSR.org
Synthetic Biology deliberation aid	✔			Forum for the future .org
Designing for values: a reflection tool to embed values in your product				TUDELFT (NL)
Techno-moral vignettes/scenarios: Exploring moral aspects of future technologies	✔			Rathenau Instituut (NL)
Gender equality, toolkit to improve gender equality in the organization strategy			✔	Australian government
Stage-gate model	✔		✔	Stage Gate Int
Sustainability method selection tool	✔			RIVM (NL)
Safe Innovation Approach: balancing risks, benefits and costs of nanomaterials	✔		✔	NanoReg 2 Project
Licara NanoScan: Integrating risk assessment and life-cycle analysis for nanomaterials	✔			LICARA project (EU)
Trusted environment: creating a safe (technical) environment for sharing information and data	✔			Public Impact company

* AR: Anticipation & Reflection; IN: Inclusiveness; RE: Responsiveness

SWOT analysis for RRI implementation in companies

Based on PRISMA experience and reflection provided so far, an attempt to provide a summary of Strengths, Weaknesses, Opportunities and Threats (SWOT) of RRI implementation in industry is provided in Table 8. Further details are provided in PRISMA deliverable 5.1.

Table 8: SWOT analysis for RRI implementation

	Helpful to achieve the objective	Harmful to achieve the objective
Internal origin	**STRENGTHS**	**WEAKNESSES**
	• Create value • Motivate workers • Offer competitive advantage • Strengthen relations with all stakeholders • Increase trust among stakeholders • Increase the social value/impact of R&D • Strengthen quality of innovation at industrial level • Ensure compliance with qualified norms and standards • Identify new market needs • Potential to communicate benefits and risks of products • Increase transparency in product development	• Limited awareness and skills on the RRI concept • Additional bureaucratic burden, lack of resources (particularly for SMEs) • Low perception of tangible impact on product development • Lack of integration of RRI across the company functions • Internal boycott from some functions in the company • Difficulties in measuring associated costs • Adding excessive extra costs to product development • Intellectual Property Rights • Misuse of the concept (checkbox exercise)
External origin	**OPPORTUNITIES**	**THREATS**
	• Improve product quality, desirability and acceptability • Improve product sustainability, safety and reliability • Increase customer satisfaction • Improve effect on quality of life and health of customers – by addressing existing social needs • Improve efficiency (e.g. use of resources, decision-making process) and cost reduction on a medium/long term • build corporate image and reputation • Improve market penetration, profit • Facilitate the access to financial support	• Difficulties in engaging with stakeholders • Possible slowdown or even premature stop of innovation • Few practical examples available from industry (case studies, applications) • Lack of engagement along the value and supply chain • Lack of endorsement by partners and suppliers • Seen by stakeholders as a “window dressing” exercise • Lack of incentives (at policy and regulatory level)

Criteria for impact analysis of RRI actions

A model of questionnaire for the self-assessment of the impact of the RRI actions is proposed in Table 9. It is structured in a set of five questions, based on lines of evidence (LoE), plus a sixth question related to the direct costs of the RRI actions. Each of the five questions is detailed by a set of sub-questions (criteria). Note that Q5 refer to economic criteria related to the product development (e.g. time to market), while Q6 refer to the costs of performing the RRI action (e.g. doing stakeholder engagement activities, establishing an ethical and social advisory board, etc.).

For each RRI action, the product/project manager should evaluate the impact of each criterion. A three-score scale ("positive, neutral/irrelevant, negative" for the questions 1 to 5; "low, medium, high" for question 6 on costs of the RRI action) is used, that could be visualized using emoticons (as in "sentiment analysis" techniques[8]). An example of what could be the outcome of the method is provided in the self-assessment matrix in Table 10 (based on a generic set of three actions A1,2,3). The methodology is further described in PRISMA deliverable 5.1..

Table 9: Description of the questions and sub-questions (criteria) proposed for the self-assessment of the impacts (benefits, barriers, costs) of the uptake of RRI actions

Main questions (Q)	Criteria (C)	Impact of RRI action (s)
Q1: Scientific & Technological Line of Evidence	- Q1.1: Inspire technological innovation - Q1.2: Feasibility of the technology solution - Q1.3: Degree of technological innovation - Q1.4: Product quality (performance/efficiency) - Q1.5: Product reliability - Q1.6: Extend the product life cycle	- Positive - Irrelevant - Negative
Q2: Ethical & Societal LoE	- Q2.1: Product acceptability - Q2.2: Product safety - Q2.3: Product environmental sustainability - Q2.4: Effect on quality of life and health of customers - Q2.5: Product related services and guidance (e.g. ethical protocols) - Q2.6: Address user's needs and rights' (e.g. privacy, data ownership, etc.) - Q2.7: Trust with/avoid conflicts with business partners, suppliers and end-users	- Positive - Irrelevant - Negative
Q3: Strategic LoE	- Q3.1: Competitive advantage - Q3.2: Corporate image - Q3.3: Transparency on product qualities - Q3.4: Customer satisfaction, meeting new consumers' needs or requests - Q3.5: Building legitimacy and gain consumer loyalty on the product - Q3.6: Improve relationships with partners, suppliers and sub-suppliers - Q3.7: Fulfil ethical and social requirements (e.g. for access to funding)	- Positive - Irrelevant - Negative
Q4: Organizational LoE	- Q4.1: Allocation and deployment of resources (e.g. human resources) - Q4.2: Team cooperation and motivation for product development - Q4.3: Address regulatory barriers - Q4.4: Safety at the workplace - Q4.5: Risk management - Q4.6: Gender and diversity contribution to product development - Q4.7: Avoid irresponsible behavior	- Positive - Irrelevant - Negative

[8] The "sentiment analysis" aims to determine the attitude of a subject with respect to a specific topic or the emotional reaction to a document or an event. The attitude could be an emotional state but also a judgment or evaluation

Q5: Economic LoE	- Q5.1: Product cost - Q5.2: Time to market - Q5.3: Market penetration - Q5.4: Market size - Q5.5: (Favored) access to financial support - Q5.6: Profit - Q5.7: Human Resources	- Positive - Irrelevant - Negative
Q6: RRI action costs	- Direct costs to perform the RRI action	- Low - Medium - High

Table 10: Example of a matrix for the self-assessment of the overall impact of RRI actions, based on specific criteria for product development. Assessment is done using emoticons, as in sentiment analysis

IMPACT OF RRI ACTIONS ON CRITERIA	IMPACT OF RRI A1	IMPACT OF RRI A2	IMPACT OF RRI A3
Q1: Scientific & Technological Line of Evidence	🙂	🙂	😐
Q2: Ethical & Societal LoE	🙂	🙂	🙂
Q3: Strategic LoE	😐	😐	🙂
Q4: Organizational LoE	😐	😐	🙂
Q5: Economic LoE	☹	😐	🙂
Q6: Direct costs of the RRI action	🙂	🙂	☹

Tools for materiality and stakeholder analysis

Different studies and projects developed tools supporting materiality and stakeholder analysis.

Some of them are useful to identify the most relevant issues or the business areas that could benefit the most from the application of RRI practices, or to what extent a company practices are aligned with RRI principles and how to move the innovation process ore responsible.

This is the case, for example, of the RRI self-check tool developed by the Compass project, that allows to analyze the company innovation process from different perspectives (the management, the idea generation and research, the development and testing and the market and impact) and find the most relevant issues from the RRI point of view[9].

Other tools can be useful to visualize the different issues and help in analyzing them. This is the case of the materiality matrix (see Figure 4), where for each issue the relevance to both the stakeholders and the organization has to be estimated, based on the impact it could have[10].

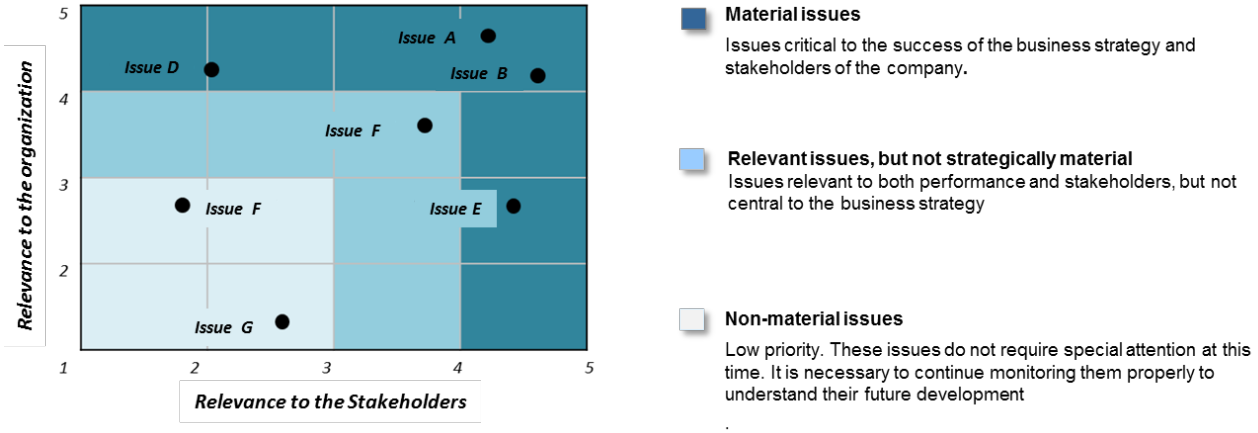


Figure 4: Example of a materiality matrix

Use a range from 1 to 5

1 - Not significant: the topic has no impact on the organization or on the decision-making process of Stakeholders

2 – Little significance: the topic has little impact on the organization or on the decision-making process of Stakeholders

3 - Significant: the topic has an impact on the organization or on the decision-making process of Stakeholders

4 - Very significant: the topic has a significant impact on the organization or on the decision-making process of Stakeholders

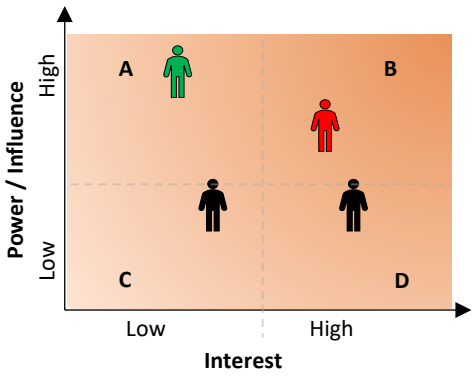
5 - Priority: the topic has a strong impact on the organization or on the decision-making process of Stakeholders

When it comes to stakeholder analysis, several steps can be taken. One of these steps is stakeholder mapping, which is a visual exercise and analysis tool that can be used to further determine which stakeholders are most useful to engage with. Stakeholder maps can be visualized based on several criteria, for instance: the level of influence against willingness to engage, type of stakeholder against level of influence, or capacity to engage and knowledge of issues against expectations. It is important to clearly set the criteria for mapping stakeholders in accordance to what is the aim of the engagement. Other criteria can be represented through dimensions and/or colors.

A practical example is presented in Figure 5, using a matrix tool

[9] Compass project - https://innovation-compass.eu/self-check/

[10] UNI/PdR 18 Social responsibility in organizations - Guidance to the application of UNI ISO 26000



Categorize stakeholders according to their potential interest in and influence on the goal, and place them on the grid accordingly (according to a realistic assessment and not based on your personal assessment of where they should be). When plotting positions on the grid, consider marking stakeholders who you see as advocating or supporting your initiative in green, and those whom you expect to block or criticize your initiative in red.

Figure 5: Example of the Interest/ Influence grid

A: **If important to engage, raise their interest**: High-power. Low-interest stakeholders: at least these stakeholders should be kept informed. Important to build a good relationship if there is no need to involve them directly. How actively these stakeholders should be pursued needs to be driven by the importance of having them involved in the dialogue.
B: **Engage**: High-influence, high-interest stakeholders: these are the stakeholders that efforts need to be made in order to engage fully
C: **Do not engage** (at least, not at the beginning): Low-influence, low-interest stakeholders: Do not involve them in the stakeholder event, but review this approach periodically, because their status can change.
D: **If important to engage, strengthen their capacity to get heard:** Low-influence, but interested stakeholders: If these stakeholder's interest is high, there must be a reason. Often these stakeholders have important information, perspectives or experiences. But they may lack the capacity to make their voices heard, so they need support in doing so. Stakeholders in this quadrant can become important supporters of the Stakeholders event. Engage them, support them and keep them adequately informed to keep their level of interest high.

The use of this grid is particularly helpful in determining what type of engagement process is required. The exercise can also be done using Power/Interest on the axes for instance.

Another type of tool is the ring stakeholder map (see example in Figure 6) This diagram generally starts on the micro-level, for instance with the identification of the primary stakeholders (e.g., investors, shareholders, customers, directors, employees, suppliers) and scales up to a meso and macro-level were secondary (e.g., government, media, local communities, activists) and contextual stakeholders (e.g., natural resources, past/future generations).

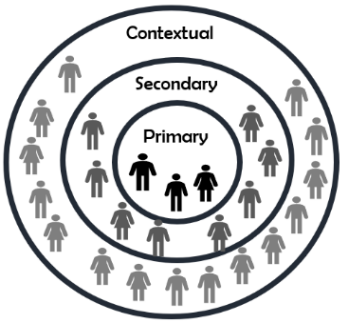


Figure 6: The ring stakeholder map

Other tools and recommendations can be found in the PRISMA project RRI tool-kit[11] and in PRISMA deliverables D4.1 and D4.2.

[11] http://www.rri-prisma.eu/toolkit/stakeholder-maps/

Methods for stakeholder engagement

There are different methods for stakeholder engagement depending on the issue that has to be discussed, the group or stakeholder to be engaged, the level of engagement (Inform, Consult, Involve, Collaborate) the desired outcomes and, in some cases, the topic itself.

Based on PRISMA experience (deliverables 4.1, 4.2) and analysis, in Table 11 some examples of methods for stakeholder engagement are provided, together with a brief description of the level of engagement, the methodology and the expected outcomes.

Table 11: Methods for stakeholder engagement

Methods	Level of engagement	Description	Expected Outcomes
Conferences and presentations with selected stakeholders	- Inform - Involve	- A formal meeting of people with a shared interest where experts provide information to a specific target (even large) audience.	- Stimulate dialogue
Focus groups	- Consult - Involve	- Discussion in a small (4 to 12 members) group of stakeholders facilitated by a skilled moderator	- Obtain a range of insights (people's attitudes, beliefs, desires, reaction) in a relaxed, non-threatening environment
Workshops	- Consult - Involve - Collaborate	- Single, short event designed to introduce or teach participants practical skills, techniques, or ideas which they can then use in their work or their daily lives. Generally small groups, allowing everyone some personal attention and the chance to be heard.	- Obtain feedback from participants - Collect opinions, values, needs, concerns about the topic and related issues - Generate new ideas and ways to improve the material introduced
World Cafè	- Consult Involve - Collaborate	- Discussion in few small groups and multiple rounds. Host introduces the process and the "Cafè etiquette". - After the first round, people are free to change the table for the next round - Each round starts with a question designed for the specific context and purpose - At the end, results of single groups are shared in a plenary discussion.	- Generate new ideas, joint decision making, key strategic issues, new ways for collaboration, etc. - Reflect on implications of a complex issue - Identify specific steps for further exploration and implementation - Graphic recording of people's ideas and expressions in words, images and colours, to be shared as a framework or guide
Fish Bowl exercise	- Involve - Collaborate	- Form of dialog to discuss specific topics in large groups. Few chairs are arranged in an inner circle (the fishbowl). Few participants are selected to start the conversation, sitting in the fishbowl, while the others are sitting outside (all around). The moderator introduces the topic and who is in the fishbowl discusses, while who	- Collect opinions, values, needs, concerns about the topic and related issues - Reflect on implications about a complex issue - Generate new ideas, joint decision making, key strategic issues, new ways for collaboration, etc.

		is outside listens. Anyone is allowed to join the conversation by occupying an empty chair, or tapping the shoulder of the person (not talking) they want to replace. - At the end, the moderator closes the fishbowl and summarizes the discussion.	
Co-creation/co-design	- Involve - Collaborate	- Joint creation and evolution of value with stakeholders, intensified and enacted through platforms of engagement. - In order to be successful, the process needs to be transparent and stakeholders need to have access to the company data on the co-creation topic.	- Share specific and detailed information in order to allow a proactive creation - Identify values, needs, concerns, etc. - Generate new concepts and ideas - Joint value creation based on stakeholders' experiences - Collect, share and spread of ideas (e.g. design) - Unexplored ideas emerge because of open conversations
One-to-one interview	- Involve - Consult	- The list of issues to be addressed or questions to be asked can be presented in a structured or semi-structured way	- Collection of detailed information on a specific matter or sets of issues
Surveys	- Consult	- Data collection on a specific topic(s). Predominantly, data is collected by self-completion questionnaire or by (semi) structured interviews	- Collection of a data set that allows the identification of patterns of relationships between the topics

Examples of RRI Key Performance Indicators

Identification and measurement of indicators to monitor the level implementation of RRI principles and actions at company level could facilitate long-term adoption of RRI. In particular, it could help to align RRI activities with key business drivers and processes, stimulate continuous improvement of RRI "performances", and allow consideration of RRI aspects in usual sustainability reporting at company level.

In PRISMA a set of 10 RRI Key Performance Indicators (KPIs) have been developed, selected and tested together with the pilot companies. The KPIs are based on literature review, interactive sessions with individual companies (pilots), on-field observation and auditing, monitoring of RRI-KPI within eight companies, meta-analysis of data, and self-reflection and auditing by internal and external reviewers before the pilot started and after the pilot ended.

These indicators should be considered as indicative, and a starting point to develop more specific KPIs tailored to the specific needs of a company. The table provides an overview of PRISMA RRI KPIs. Further details are provided in PRISMA deliverables D3.1, D3.2, and D3.3.

Table 12 Examples of quantitative indicators to monitor implementation of RRI principles at company level

	Item	RRI KPIs	Examples of quantitative parameters to measure KPIs
Anticipation & Reflection	1	Awareness of moral values	- Nr. of training sessions/meetings per year to learn and reflect on moral values connected to innovation strategy and core business
	2	Awareness of ethical issues of innovations	- Nr. of training sessions/meetings per year aiming to reflect on integration of social and ethical values into specific R&I/R&D projects
	3	Does the company embed moral values in its innovations?	- RRI principles formally integrated into the company's mission and vision (e.g. ethical code of conduct)
			- Nr. of R&I/R&D projects per year where moral values are actively and included into innovation strategies and technological design
	4	Does the company (actively) anticipate social effects of its innovations?	- Nr. of R&I/R&D projects per year where internal/external stakeholders were involved from the early stages in product development
			- Nr. of consultancy initiatives with other innovators and external advisors to discuss and identify social impacts of R&I/R&D projects
Inclusiveness	5	Stakeholder engagement	- Nr. of stakeholder engagement initiatives organized per year by the company
			- Nr. of R&I/R&D projects per year where active stakeholder engagement is foreseen into R&I/R&D plans
			- Nr. of R&I/R&D projects per year where engagement with end-users has been performed
	6	Gender Diversity	- Percentage of men and women involved in R&I/R&D function/teams in the company

Responsiveness	7	Transparency and accountability about RRI-relevant choices	- Formal communication strategy established at company level to ensure most relevant RRI choices are explained in key company documents and/or the website
			- Nr. of patents per year aiming to integrate non-financial values
			- Nr. of open access publications
			- Nr. of events or webpages or channels in social media (or similar) disseminating project results to the general public
	8	Learning mechanisms to address public and social values in product development	- Nr. of user-centered approaches per year formally integrated into the company innovation model (e.g. user-centered design, co-creation)
			- Nr. of user experience tools per year carried-out to respond (new) societal demands and developments
	9	Capacity to align to societal goals	- Nr. of R&I/R&D projects per year addressing socially/ethically-oriented products/services
	10	Active monitoring of RRI impacts	- Percentage of R&I/R&D projects per year that apply impact analysis strategies (e.g. risk management, ethical/social impact analysis, etc.)
			- Formal external auditing procedures (at least yearly basis) in place to monitor non-financial values of the company

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PRISMA RRI-CSR Roadmap
Part B- pilots roadmaps

Deliverable 5.2

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List of abbreviations

<PRISMA>	<Piloting RRI in Industry: a roadmap for tranSforMAtive technologies>
< CSR >	<Corporate Social Responsibility>
< RRI >	< Responsible Research and Innovation >
<SMEs>	< Small or Medium-sized Enterprise >
<KPIs>	< Key Performance Indicators >
<R&D>	< Research and development >
<ELSI>	< Ethical, Legal, Social Impacts>

Table of contents

1. Introduction

The overarching goal of the PRISMA project is to help companies implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies, and to provide evidence on how RRI can improve their innovation processes and products and help companies to gain trust from society and build resilience, thus strengthening their position on the market.

The PRISMA project worked for two years with eight pilot companies, exploring and experimenting RRI methods, tools and actions in specific Research and Innovation (R&I) projects on transformative technologies, including in particular nanotechnologies, biotechnologies, the Internet of Things and autonomous vehicles (see table).

The companies involved were active in different technologies and sectors, and included small and medium companies, public-private partnerships and a cooperative R&I project.

During the pilot, the PRISMA partners have supported the companies in implementing RRI actions adopting two different strategies. By providing external advice and consultancy to the company during the design of its specific RRI roadmap and by having an embedded ethicist within the company co-operating with the different organization's functions. Cornerstones of this action were:

- Performing ethical analysis, to reflect on ELSI of the R&I project
- Realizing awareness-raising and training initiatives for R&D personnel
- Design for values, value scenarios to inform R&I products design
- Advising on implementation of RRI and CSR tools and methodologies
- Organizing dialogues and co-creation initiatives with stakeholders
- Engaging with business partners to address RRI aspects

Based on this experience, eight "RRI roadmaps" have been developed, aiming to help these companies to implement RRI in their innovation processes, in order to deal with uncertain and sometimes partly unknown risks (anticipate), inform product development by dialogue with stakeholders (inclusion and reflection), and address public and ethical concerns of transformative technologies (responsiveness).

The pilot activities to implement RRI followed a typical Plan-Do-Check-Act/Adjust approach, that has been used as a starting point to define the structure and contents of the RRI roadmaps. These RRI roadmaps have been designed following an iterative revision process, paralleling the experimentation performed with the pilots. The pilot RRI roadmaps presented in this report has been aligned and refined based on the final version of the exemplar roadmap methodology (part A of this report).

For each of the eight pilot companies, a case description and the roadmap are reported, including the following information:

- Case description
    - The Company
    - RRI commitment
    - Context
    - Materiality & experimentation
    - Validation aspects (criteria for impact analysis)
- RRI Roadmap
    - RRI VISION
    - R&I Technologies and products
    - Drivers and challenges for RRI

- Risks and barriers to be addressed by RRI actions
- RRI actions
- Roadmap design

Though a similar approach has been used to all the pilots, the methodology has been also adapted to the specific situation. This is reflected in differences in contents and outcomes across the different roadmaps.

Terminology and definitions used within each description refer to the exemplar roadmap (part A of this report). A more detailed description of the experience performed during the pilot is reported in PRISMA deliverable D2.4.

Pilot company	Type of company	R&I project	Technology	Country	PRISMA strategy	Consortium partner
Colorobbia Consulting	SME	In-house and public funding	Nano-technology	Italy	External support	Airi
Laboratori Archa						
Evolva		In-house	Synthetic biology	Switzerland		TU Deflt
Spectro			Internet of Things	The Netherlands		
Aerialtronics			Drones			
WMG: Hub of All Things		In-house and public funding	Internet of Things	UK	Embedded ethicists	University of Warwick
WMG: RDM			Autonomous vehicles			
Bisigodos	Public-private partnership	EU-financed project	Industrial Bio-technology			

2. Colorobbia Consulting

2.1. Case description

The Company

- Gruppo Colorobbia is specialised in the production and distribution of raw materials, semi-finished products and chemicals for the ceramics and glass industry.
  Colorobbia Consulting S.r.l. is the technology service company of Gruppo Colorobbia, with activities on research, chemical and chemical-physical analysis, compliance with environmental and safety regulations, IT and process plant engineering. Its mission is the research and development, prototyping and production of nano-based products to be used in the industrial sectors of pharmaceutics, nanomedicine, coatings and environmental protection.
  The core values of the company include: quality and excellence in R&I; attention to environmental health and safety (EHS) issues in the R&D and production processes; respect of ethical standards in R&I; development of innovative solutions to tackle societal challenges. These values guide the overall business model of the company.

RRI commitment

- The RRI PRISMA pilot has been endorsed by one of the Executive Managers and the R&D manager
- Motivation for RRI: Better understanding (anticipating) potential ethical, legal and social risks and benefits, addressing uncertainties in existing and future developments in norms and standards, and exploring ways to ensure societal acceptability of the final products of the NanoMed project.

Context

- Type of pilot organization: SME
- Country: Italy
- R&I project selected: NanoMed: Advanced nano-based theranostic platform for cancer and nervous system diseases.
- Technology: nanotechnologies
- Regulatory regimes relevant for NanoMed: nanomaterials, Advanced Therapy Medicinal Products (ATMP), medical devices
- Type of R&I activities: in-house and cooperative research
- Type of business: business to business
- Time to Market (indicative): 5-10 years
- CSR policies: in-house corporate sustainability policy
- Gender balance and gender policy in R&D: similar composition of R&D personnel in terms of men and women, no relevance of gender & diversity in recruitment criteria and selection of R&D personnel
- RRI Maturity Level: Strategic

Materiality & experimentation

- Key stakeholders: company (R&D, Quality and Management), R&D partners (research centres and academia, hospitals), business partners (public and private investors, suppliers), market clients and end-users (hospitals, healthcare professionals, patients associations, patients, advocacy groups), policy makers and regulators (healthcare sector), society (media and the public)

- Key ethical, legal and social issues: product efficacy, safety (use of nanomaterials in particular), excellence in R&D, ethics (respect of patients' rights), patient-centric procedures for both clinical trials and cure; respect of the principles of precaution, beneficence, dignity, informed consent, data protection and data ownership

- RRI actions selected for the PRISMA pilots [1]: RRI Training, ethical and social analysis, stakeholder dialogue

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on NanoMed products are[2]:
  - Q1.1: Inspire technological innovation
  - Q2.2: Product safety, Q2.4: Effect on quality of life and health of customers, Q2.5: Product related services and guidance (e.g. ethical protocols)
  - Q3.3: transparency on product qualities; Q3.7: fulfil ethical and social requirements
  - Q4.3: address regulatory barriers, Q4.5: Risk management;
  - Q5.2: Time to market, Q5.7: Human Resources (use of)

2.2. RRI Roadmap

RRI VISION

Realize a personalized, patient-centric and point of care therapy, for a highly effective, accessible and affordable treatments of severe diseases.

R&I Technologies and products

NanoMed, is a large research project based on in-house resources from the company and funding by different cooperative projects. Its aim is the development of a technology platform providing an integrated and modular system, for the diagnosis and treatment (theranostic) of cancer and nervous system diseases. It is a nanotechnology-based system, using a combination of targeted and controlled drug delivery, hyperthermia and radiofrequency treatment and laser imaging methods.

The technology platform will lead to different products, including a contrast agent, a formulation (drug), a cell therapy system and a portable and integrated medical device to produce the cell therapy system.

Drivers and challenges for RRI

Drivers:

- **Demand for better diagnosis and increased efficacy in therapies** for cancer and nervous systems diseases
- **Entry into new markets, diversify company product portfolio**

Challenges:

- **Personalized and precise diagnosis and treatments, significantly increasing patient survival and life quality**
- **Ensure accessibility (point of care), equity and affordability of treatments**
- **Patient-centric procedures, for both clinical trials and cure**
- **Need for long term research investments**

[1] Further information available in PRISMA deliverable D2.4: Responsible innovation in practice: experiences from industry

[2] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

Risks and barriers to be addressed by RRI actions

- Regulatory uncertainties
- Ethical and social concerns, addressing patient's rights (precaution, safety, beneficence, dignity, informed consent, data ownership, transparency)
- Risks (potential/perceived) of use of nanomaterials into the body
- Safety of nanomaterials along the product life cycle
- Long-term efficacy and reliability of the therapy (in particular in relation with the use of nanomaterials)
- Societal acceptability, lack of trust in the product (in particular by professionals and patients)
- Mismatch of personalized therapy approach with the existing healthcare system
- Complex business eco-system
- Resources and competences for RRI actions

RRI actions

Reflection & Anticipation:

- **Ethical and social impact analysis**, to pursue key social values and increase social impact of NanoMed products. Activities within PRISMA, including training and reflection on RRI with company staff facilitated by RRI experts (project partners), helped the company to reflect on RRI aspects of the product. These included issues related to product efficacy, safety of the product, excellence in R&D, ethics (respect of patients' rights) and patient-centric procedures for both clinical trials and cure; transparency about the ways of production and use nanomaterials in the product; issues of risk-benefit of personalised therapies, affordability, accessibility of the treatment

Inclusiveness:

- **Stakeholder dialogue:** a dialogue event with most of the key stakeholders identified in the materiality analysis has been organized to shape the contents of the NanoMed roadmap
- **Co-design and cooperation with authorities (cell therapy) and with patients (e.g. for clinical trials)**: regulatory monitoring in the areas of ATMP, medical devices and nanomaterials; early cooperation with EU and national authorities on medicinal products, ATMP and nanomaterials; dialogue on ethical and social impacts with actors along the value chain of the R&I project; cooperation with national and local authorities and ethical committees on issues related to animal testing (and alternative methods to animal testing); plan and design protocols to ensure respect of patients' rights, including appropriate procedure for the data management and the informed consent related to data collected during clinical trials and therapy; consider novel approaches to design clinical trials, taking into account the peculiar aspects of personalized medicine; consider gender aspects in the definition of clinical trials; Implement a long-term risk management plan in the post-marketing phase, in order to oversee medium and long term impacts of the therapy on patients

- **Early Assessment and dialogue on business models/costs/benefits with investors and the healthcare system:** early analysis of cost-benefit impacts of the new therapies, regular screening of potential business models for personalized therapies, also based on assessment of benchmark products; early cooperation with Research Contract Organizations to analyse socio-economic impacts and potential (responsible) business models; dialogue and cooperation with potential public and private investors, including the health-care system (e.g. local authorities and hospitals).

- **Create a communication and dialogue strategy toward professionals, patients and society:** design an informed consent protocol together with health-care professionals, patients associations, and ethical committees; create informative events targeted to health-care professionals & patients; identify appropriate communication means and channels to inform the wider public on NanoMed technologies and products; favour the principle of "return on investment" of all stakeholders engaged in the NanoMed project.

Responsiveness:

- **Early use (research) of qualified standards and quality procedures all along the R&D and production process**

- Strict **safe by design approach for** NM in product development

- **Research & modelling of the mechanism of action (long-term efficacy)** of the therapy to ensure system reliability

- **Establishment of an ethical and social monitoring board to oversee project activities:** Engage a multi-disciplinary panel of independent experts and end-users in order to assist the project in strategic choices on ethical, legal and social aspects (e.g. risk-benefit evaluation,) taking into account also technical developments (e.g. safety of nanomaterials) and socio-economical aspects

Roadmap design

The aspects relevant for the RRI uptake by the company, covering all the period until the commercialization and use of the product, have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 1).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake, being suitable for implementation in the context of the overall development strategy of the NanoMed project. Some short-term actions were already planned by the company, other have been implemented thanks to the cooperation with PRISMA.

A barrier to RRI implementation is the human and financial resources needed to implement the roadmap. However, the overall balance is positive, an RRI approach is vital to improve functionalities, quality and reliability, acceptability, of the NanoMed technologies and products.

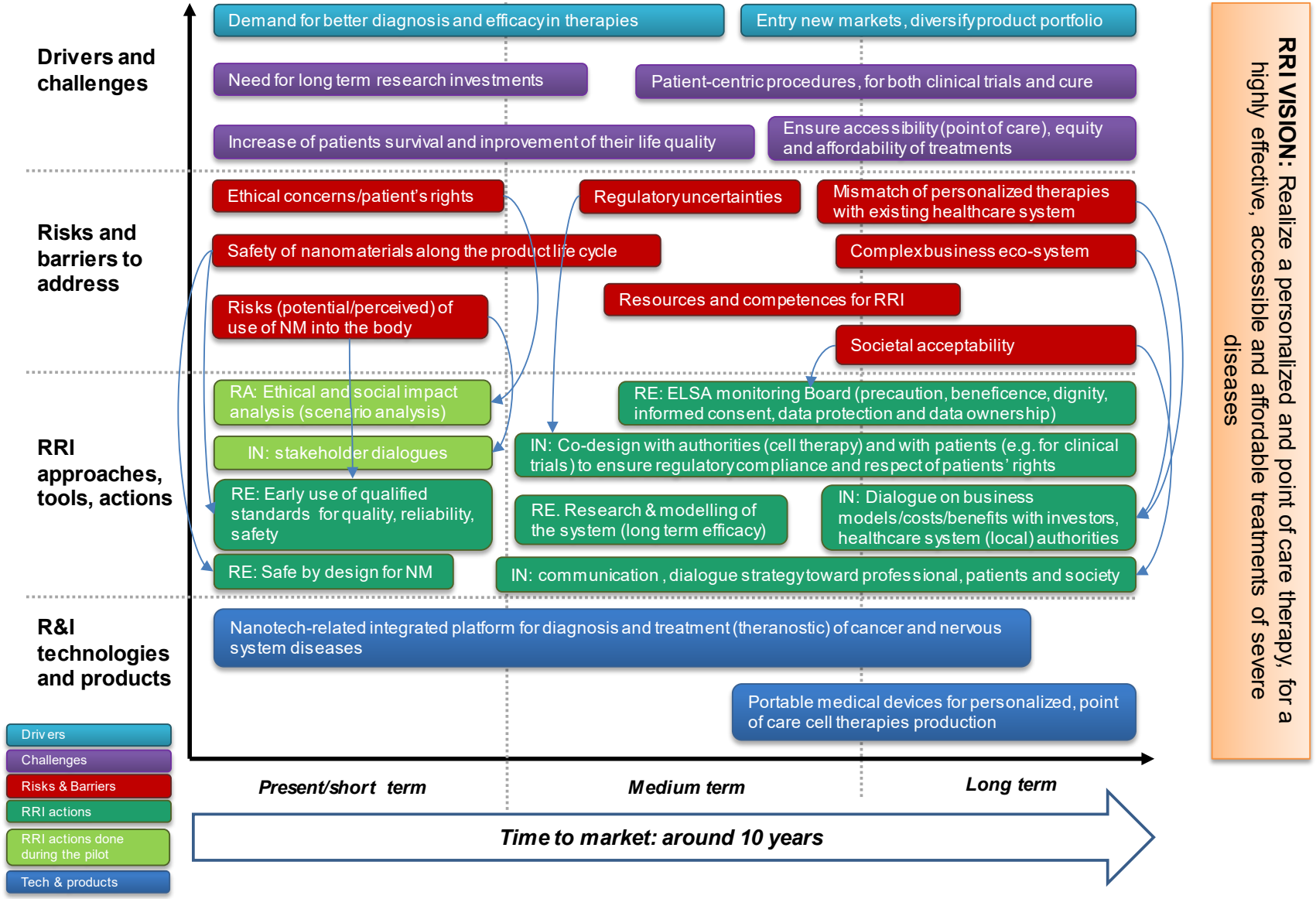

Figure 1: Colorobbia Consulting, PRISMA RRI roadmap

3. Laboratori Archa

3.1. Case description

The Company:

Laboratori Archa S.r.L (Archa) is a small-to-medium size enterprise (SME), with the mission to provide assistance, technological innovation and know-how to companies to enable them to produce while respecting the human health and the environment, preventing risk and complying with moral and ethical principles.
The support spans over all the stages of the innovation process: outlining/definition of the idea, the research and development phases, prototyping, start-up and industrialization.

RRI commitment

- The RRI PRISMA pilot has been endorsed by the Executive management, and the R&D and quality managers
- Motivation for RRI: address risk and risk perception related to use of nanomaterials all along the life cycle of the product, strengthen product acceptability, address normative and regulatory compliance

Context

- Type of pilot organization: SME
- Country: Italy
- R&I project selected: NanoCube
- Technology: nanotechnologies
- Regulatory regimes relevant for NanoCube: nanomaterials, cosmetics, medical devices
- Type of R&I activities: cooperative research
- Type of business: business to business
- Time to Market (indicative): 3-5 years
- CSR policies: Archa is certified OHSAS 18001 (Occupational Health and Safety Assessment), SA8000 (Social Accountability), UNI EN ISO 14001 (environmental management), UNI EN ISO 9001 (quality management).
- Gender balance and gender policy in R&D: similar composition of R&D personnel in terms of men and women, no relevance of gender & diversity in recruitment criteria and selection of R&D personnel
- RRI Maturity Level: Strategic

Materiality & experimentation

- Key stakeholders: NanoCube research partners, technology developers, nanomaterials producers, dermo-cosmetic and medical devices manufacturers, hospitals, retailers, certification bodies, consumers

- Key ethical, legal and social issues: product efficacy, safety and safe production, risk perception and user acceptability (in particular for nanomaterials), improved quality, affordability, compliance with sustainability norms (workers' rights, supplying of raw materials, reduced environmental impact in processing and production)

- RRI actions selected for the PRISMA pilots [3]: RRI Training, ethical and social analysis, stakeholder dialogue

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the NanoCube products are[4]:
    - Q1.1: Inspire technological innovation
    - Q2.1: Product acceptability; Q2.2: Product safety;
    - Q3.3: Transparency on product qualities; Q3.4: Customer satisfaction, meeting new consumers' needs or requests; Q3.5: Building legitimacy and gain consumer loyalty on the product;
    - Q.4.4: Safety at the workplace; Q4.5: Risk management
    - Q5.7: Human Resources (use of)

3.2. RRI Roadmap

RRI VISION

Create nano-based dermo-cosmetic products, based on ethically acceptable and sustainable production methods and on a safe and more effective use of natural and organic ingredients.

R&I Technologies and products

The NanoCube project, coordinated by Archa and Techa (Tuscany region funds POR FESR 2014-2020) develops innovative technologies aimed at producing nanocapsules and nanosystems providing controlled release of bioactive agents for cosmetic and biomedical applications.
A key research challenge is the exclusive use of natural ingredients, including the nanocapsules, and processing steps avoiding the use of chemical (synthetic) solvents. The final dermo-cosmetic product is expected to fulfil specific voluntary international certifications for organic and natural cosmetics.
Final products of NanoCube include: a dermo-cosmetic product based on controlled released of bioactive agents, that might be further developed in a medical device (class I) for anti-inflammatory dermal treatments; an electrospinning device/process for nano-capsule production; a medical device for lesion care (class II medical device) using nanowires produced by electrospinning.

Drivers and challenges for RRI

Drivers:

- **Demand for more eco-friendly and organic based dermal products**
- **More efficient use of natural substances**
- **Reduce use of antibiotics**
- **Reduce risks for workers in handling active substances**

Challenges

- **Transparency and open communication to consumers**
- **Ensure workers' and consumers' rights all along the supply chain and product life cycle**
- **Efficacy, reliability and quality vs. conventional detergents**

[3] Further information available in PRISMA deliverable D2.4: Responsible innovation in practice: experiences from industry

[4] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

Risks and barriers to be addressed by RRI actions

- **Regulatory uncertainties (e.g. regarding NM classification)**
- **Upscale of production system for nano-capsules**
- **Risks of use of NM into the body**
- **Risk perception on nanotech of professional users and, in particular consumers of green and natural cosmetics**

RRI actions

Reflection & Anticipation:

- **Ethical and social impact analysis** (stakeholder and value inventory, design for values approaches)

Inclusiveness

- **Organize regular dialogue (co-creation) events on product development with stakeholders** in particular developers, producers, certification bodies, distributors of cosmetic products for sharing values, creating positive ethical networks, and improving acceptability of the final product:
  - A first stakeholder dialogue has been held during the Prisma project to shape the contents of this roadmap; others should be organized continue all along the product development phases.
- **Dialogue and cooperation with authorities** to anticipate potential risks and monitor regulatory development, in particular for the nano-capsule production system and the medical device product
- **Developing of a communication strategy, based on scientific evidence, to ensure transparency and quality and credibility of product claim.** Particular attention to the use of nanomaterials. Specific criteria for the strategy include:
  - Distinguishing between natural substances and synthetic substances
  - highlighting improvements in durability and efficacy of the product, and possibility to avoid/reduce the use of conservatives in the cosmetics
  - Providing indication on the safe use of nanomaterials during production, use and disposal (complementing normative requests of cosmetic regulation, requiring including nanomaterials in product labelling)
  - further emphasise in project communication aspects of gender balance in R&I as one of the strengths of the project and the company

Responsiveness:

- **Implementation of risk management systems for nanomaterials**, including use of state-of-the-art practices and standards for characterization, measurement and safety testing of nanomaterials (e.g. OECD test guidelines). Full assessment of potential exposure to nanomaterials during the production of nano-capsules, and regarding the end of life of the product
- Implementation of **computational models, pre-screening techniques and in-vitro approaches for safety assessment of the product** (in the case of medical devices, as alternatives to animal testing).
- **Certification at process and product level to promote safety, ethical acceptability and societal desirability of products**:
  - Fulfill requirements of ethical certification for the dermo-cosmetic products (e.g. COSMOS certification for organic and natural cosmetics products in Europe) and certifications concerning biological farming for production of raw materials (production of the active substance of the dermo-cosmetic)
  - Integrate in existing risk management, quality and social accountability certification at company and supply chain level, best practices for safe handling of nanomaterials in the workplace (e.g. control banding tools), and for end of life management of nano-related products

Roadmap design

The aspects relevant for RRI uptake by the company, covering all the period until the commercialization and use of the product, have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 2).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake, being suitable for implementation in the context of the NanoCube project. Some short-term actions were already planned by the company, other have been implemented thanks to the cooperation with PRISMA. Some of the RRI tools and approaches emerged by the work of PRISMA will be integrated in usual practices of the company on several R&D projects.

Participation in PRISMA, helped the company to better understood the relevance of societal values to improve the R&D process, and the need of a transparent communication and of cooperation with stakeholders to align R&D products to their needs, expectations and requirements.

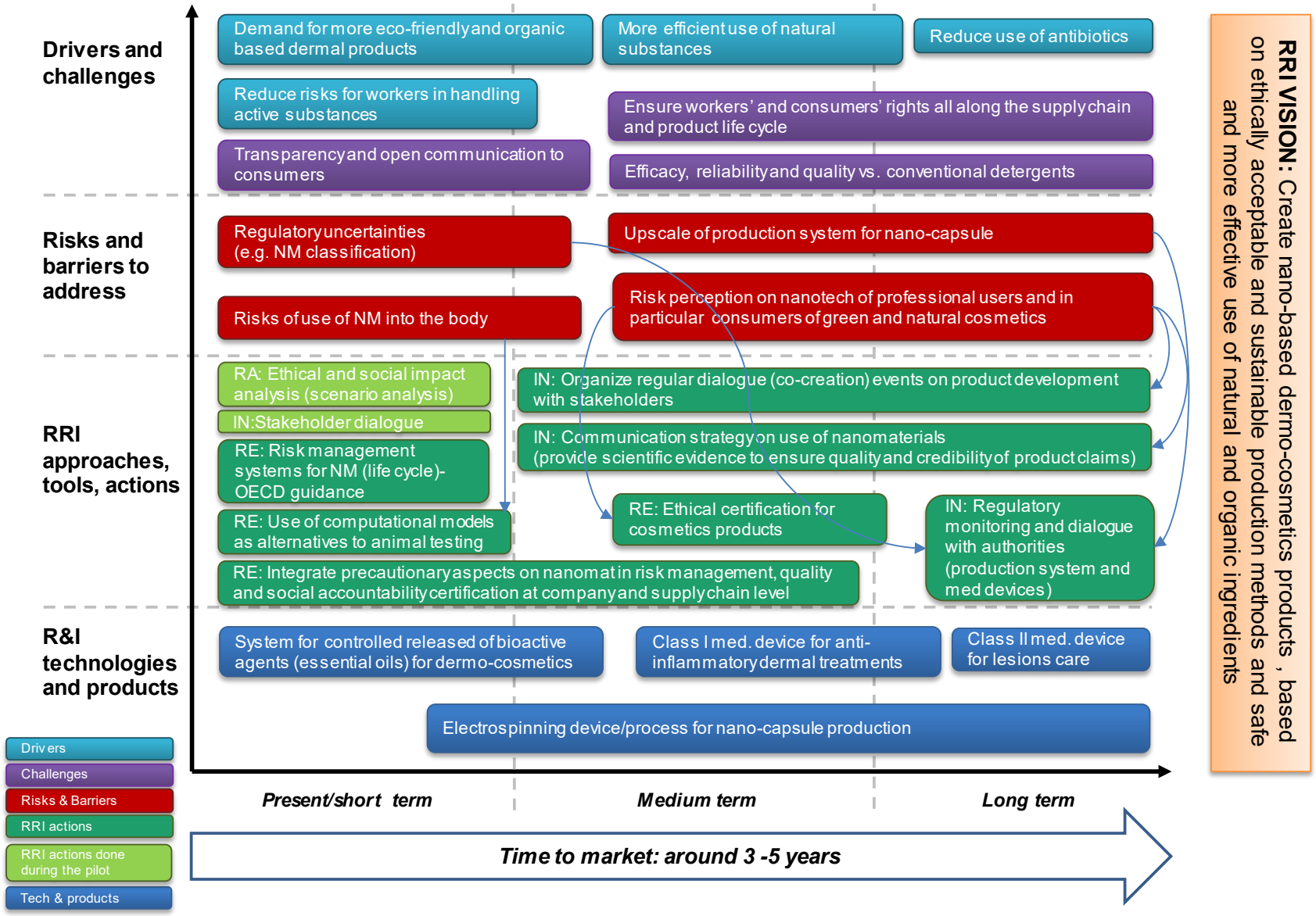

Figure 2: Laboratori Archa, PRISMA RRI roadmap

4. Evolva

4.1. Case description

The Company:

Evolva was created in 2004, as one of the first biotech firms in the world. It is a Swiss based company producing innovative, high-value, sustainable ingredients with an emphasis on the health, wellness and nutrition sectors. Evolva leverages modern biotechnology, including synthetic biology, to produce what are called yeast "strains," which are then brewed like beer in the traditional fermentation process. The purified end product contains no recombinant material. These end-products are molecularly identical to those traditionally extracted from plants, animals and petrochemicals.

Many of the substances produced by Evolva are ingredients found in the natural world that come with supply chain issues, such as originating from a rare plant or animal. These ingredients are not available at the right quality or price in a sustainable manner. Sustainability, being one of Evolva's core values, drives Evolva to focus on a re-production of these types of ingredients by combining modern genetics with traditional brewing.
Evolva's products include substances such as Resveratrol, Nookatone and Valencene. Resveratrol is an example of a product with plenty of benefits (such as its potential to slow the rate of aging of neuromuscular junctions or lungs) but rare or difficult to be extracted from wine or grapes.

Evolva has experienced resistance from some environmental organisations in the past with some of their innovations such as fermentation-produced vanillin. The company is committed to Responsible Innovation, however, so far this has not prevented resistance from some societal actors.

Commitment

- The RRI PRISMA pilot has been endorsed by the public relations Manager. Endorsement from the executive management has been intermittent, due to restructuring of the company and change of managements during the period of the pilot
- Motivation for RRI: showcase and further strengthen responsibility and sustainability efforts of the company

Context

- Type of pilot organization: SME (100 employees)
- Country: Switzerland (headquarters)
- R&I project selected: Agarwood
- Technology: synthetic biology
- Relevant regulatory regimes: Genetically Modified Organisms (GMOs) legislation
- Type of R&I activities: in-house and cooperative research
- Type of business: business to business
- Time to Market (indicative): not available (project was stopped during the pilot because of company the restructuration)
- CSR policies: Sustainability strategy, based on the UN Convention on Biological Diversity. Responsible Research and Innovation and sustainability are part of the core values of the company
- RRI Maturity Level: Defensive

Materiality & experimentation

- Key stakeholders: research partners, NGOs, industry observers, farmers and local communities, the media and the general public

- Key ethical, legal and social issues:
  - safety of genetically modified organisms: the potential threat to biological diversity if they escape to the environment
  - value chain/benefit sharing and impact on farming at local territories: risk of biotech and fermentation-derived products replacing those from small, independent farms in vulnerable communities and developing countries
  - Environmental sustainability of fermentation products: most common feedstock used for yeast is sugar, the production of which may lead to deforestation
  - information to consumers (labelling): Synthetic biology are generally not allowed to be labelled as "natural". This applies also to Evolva products, though they are chemically identical to the product that was extracted from animals or plants, and contain no trace of the genetically modified yeast used in production.

- RRI actions performed during the pilot: ethical and social analysis, work with business and social actors sharing values and create positive ethical networks

Validation aspects (key performance indicators)

- The most relevant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the Agarwood project are [5]

  - Q1.2: Feasibility of the technology solution
  - Q2.1: Product acceptability
  - Q3.5: Building legitimacy and gain consumer loyalty on the product
  - Q4.3: Address regulatory barriers
  - Q5.3: Market penetration
  - Q6.1: Direct costs to perform the RRI action

4.2. RRI Roadmap

RRI VISION:

to create a mutual understanding of a desirable innovation pathway that can benefit both the synthetic biotechnology value chain as well as other stakeholders.

R&I Technologies and products

The goal of the Agarwood project is the development of natural compounds using Evolva's yeast fermentation production platform. The goal is to create a new paradigm in the sustainable production of Malaysia's high value indigenous natural products, starting with agarwood fragrances.
Agarwood of the Aquilaria and Gyrinops variety has been used since a long time by incense and perfume makers, and traditional medicine practitioners. Despite conservation measures and concerted efforts to grow Aquilaria and Gyrinops in tree nurseries and organic tree farms, these trees are rapidly vanishing from forests due to high demand. Agarwood has been designated as an endangered species by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The production of a range of

[5] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

agarwood products by fermentation could complement the existing traditional approaches and allow a significant widening of their use without increasing the pressure on the endangered trees.
The project got underway in 2014 and been in an exploratory phase until 2018 and has been currently suspended.

Drivers and challenges for RRI

Drivers:

- **Finding replacements for the use of natural ingredients in health, wellness and nutrition products related to critical supply chains or originating from a rare plant or animal**
- **Ingredients for health and food that respect sustainability, availability of animal welfare issues**

Challenges:

- **Innovation trajectory and innovation eco-system internationally dispersed**
- **Lack of company resources for RRI due to volatile market**

Risks and barriers to be addressed by RRI actions

- **Prospective costumers are not primarily driven by sustainability**, and by mechanisms such as LCA analysis. For example, most food and beverage producers focus on price and taste. They rarely pay suppliers a premium for ingredients that come with LCA data. There is no green premium.
- **Societal debates about 'naturalness' and 'economic justice', and around synbio are highly polarized**
- **Some societal actors, such as some critical NGOs, are not open to exchange and collaboration**
- **It is difficult to establish sustainability of a product while developing the innovation, this is also due to the fact that different actors will use different criteria to establish sustainability**

RRI Actions

Reflection & anticipation:

- **Ethical analysis**, through foresight, scenario analysis, and other approaches, in order to develop a "socially ideal" business case for the R&I project (e.g. Agar Wood) .
- Further explore the opportunity to implement **Life Cycle Assessment (LCA) and Social-LCA**

Inclusiveness:

- **In the early stages of the R&I process, work with stakeholders to develop robust ethical and social framework** (sharing values and create positive ethical networks, building user-based communities of practice), for selecting the 'problematic' ingredient which deserves to be replaced by a synthetic alternative. This includes exploring how to determine what fair and equitable benefit sharing implies for stakeholders.
- Share and communicate the ethical and social framework with stakeholders and the civil society, in a societally robust and transparent way

Responsiveness:

- **Implement adaptive risk, quality and sustainability management approaches**, in order to: develop and continously update ways to demostrate whether Evolva's products are indeed more sustainable then the existing ingredients; and to re-evaluate metrics used for analysis and reporting of sustainability performances (e.g. parameters to perform LCA), to adapt them to production and product development and optimization.
- Further participate in **sustainability, social accountability, quality certification schemes surrounding the 'problematic' ingredient**, at both company and supply chain level
- Support **and invest in sustainable supply chains for the feedstock supply of the engineered yeast**

- **Realize capacity building initiatives with vulnerable actors in the value chain**, creating opportunities for vulnerable farmers in new value chains

Roadmap design

The aspects relevant for the RRI uptake by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 3).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake. If the above-mentioned issues are answered in a collaborative practice with a wide range of constructive actors, Evolva could move from a *defensive* kind of RRI to a more pro-active, confident kind of RRI. Defensive RRI is geared towards damage control and risk-management. Confident kind of RRI is geared towards the development of a robust rationale underlying and motivating all steps in the innovation chain. Such a rationale will allow for a more confident engagement with critical NGOs and concerned consumers.

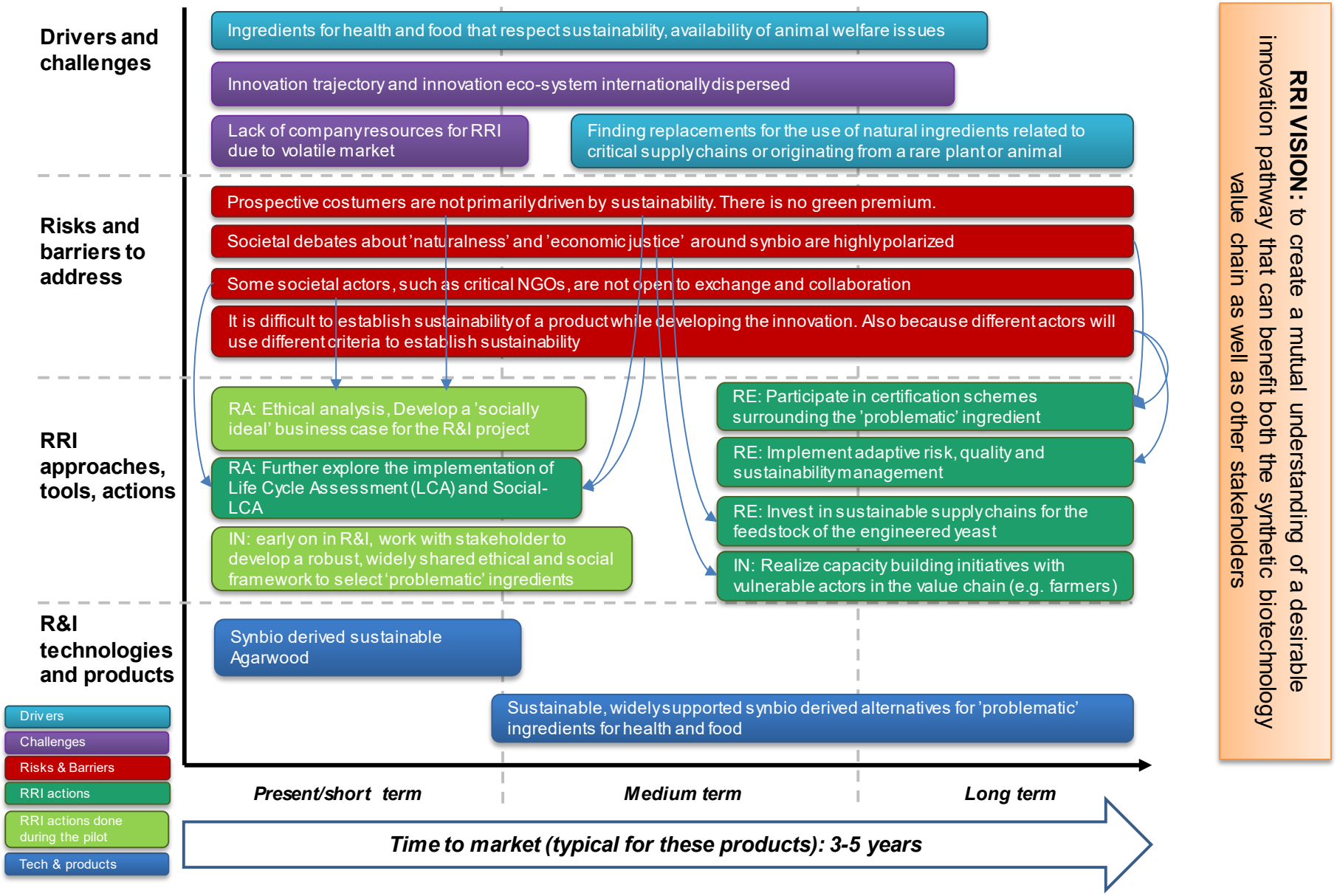

Figure 3 Evolva, PRISMA RRI roadmap

5. Spectro

5.1. Case description

The Company

Spectro is a Dutch manufacturer of cleaning agents for professional use. It is a family-owned company with about fifty employees and a small R&D department.

The company has an active Corporate Social Responsibility (CSR) policy, with a focus in particular on sustainability. The mission is 'to decrease the total environmental impact of its products as well as decrease the cost of cleaning', and the company has the ambition to become a European player in the area of sustainable cleaning agents. Spectro also successfully implemented the A.I.S.E. Charter for Sustainable Cleaning (update 2010) in 2011 throughout the company. The 'Charter' is the quality system of the European Sector Association A.I.S.E. which has many overlaps with other quality systems such as ISO 9001, ISO 14001, OHSAS 18001 and EMAS.

The company develops highly concentrated ecological cleaning agents that are combined with smart dosing systems. A main example is the brand Ecodos, a system that takes care of the exact dosage of cleaning agents, so that overdosing becomes impossible. The rationale behind this is that life cycle analyses show that a large part of the environmental impact of cleaning detergents is in the use phase. Reducing detergent use, thus, has a positive environmental impact. Moreover, it reduces costs of cleaning. The Ecodos Easy system also has a small solar panel so that it can function independently from the electricity grid. The system stores data about its use.

Commitment

- The RRI PRISMA pilot has been endorsed by both the CEO and the R&D manager
- Motivation for RRI: respecting public values and avoiding ethical problems, ensuring acceptance of innovation by stakeholders, increasing market share though adding societal value

Context

- Type of pilot organization: SME
- Country: The Netherlands
- R&I project selected: development of EcoDos in a cleaning devices system for sharing of data
- Technology: cleaning technology and Internet of Things
- Relevant regulatory regimes: cleaning detergents, General Data Protection Regulation
- Type of R&I activities: in-house and outsourcing
- Type of business: business to business
- Time to Market (indicative): 3-5 years
- CSR policies: in-house CSR and sustainability policy. Spectro also supports customers in achieving their CSR targets.
- RRI Maturity Level: Strategic

Materiality and experimentation

- Key stakeholders: cleaning products distributors; cleaning personnel; healthcare personnel; patients (and relatives); hospitals cleaning departments, purchase units, logistics departments, directions, expert infection prevention; health inspection; ministry of health

- Key ethical, legal and social issues: public/patient health and hygiene, sustainability, privacy, security, transparency (of data collection), autonomy (of cleaning personnel), reliability and trust

- RRI actions selected for the PRISMA pilots:
  - Literature study about hygiene issues in hospitals and the potential for better cleaning solutions
  - Stakeholder and value inventory and value scenarios (design for values): identification of values hierarchy, conflicting values and potential ways to deal with them

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the Ecodos project are [6]
  - Q1.1: Inspire technological innovation;
  - Q2.2: Product safety; Q2.3: Product environmental sustainability; Q2.6: Address user's needs and rights' (e.g. privacy, data ownership, etc.);
  - Q3.1: Competitive advantage; Q3.4: Customer satisfaction, meeting new consumers' needs or requests;
  - Q4.5: Risk management
  - Q5.1: Product cost; Q5.3: Market penetration;

5.2. RRI Roadmap

RRI VISION

To develop new cleaning technologies that contribute to public health and hygiene (and respect other relevant values) and offers Spectro the possibility to increase market share.

RRI technologies and products

A main technological development for Spectro is the Internet of Things (IoT). This will allow making cleaning devices connected and the collection and exchange of data. Some larger multinational companies are already developing and advertising new cleaning applications using IoT. Spectro is embarking on this development and is developing a number of IoT-based applications. Such applications will allow better maintenance and servicing (e.g. refilling in time). They also allow the collection of data about cleaning which can contribute to better or more efficient cleaning.

(T1) New version of Ecodos that can exchange information trough internet

(T2) Share data with customers: this development was based on (A5). Spectro has developed an app to more actively share data with its customers so that they can take responsibility for the frequency and quality of cleaning.

(T3) Use data for prevention (e.g. warning of potential lack of cleaning): this is the long-term perspective that might help to attain D3

Drivers and challenges for RRI

Drivers:

(D1) Increased use of IoT in cleaning

(D2) Strong commitment of the company to CSR and public values

(D3) **Adding societal value (public hygiene) may offer new business opportunities for the company**: One of the potential markets that was explored for new clever dosing systems using IoT is that of cleaning in hospitals. This market is interesting for Spectro because the company is still a smaller player in that market but would like to expand. It was found – through a literature study – that healthcare-associated infections (HAI) are a main concern in hospitals.

[6] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

(D4) The company is developing from a product provider (cleaning agents) to a technology/service provider

Challenges

(C1) Building new relationship with customers
(C2) Acquiring expertise on IoT and ICT
(C3) Increase RRI expertise

Risks and barriers to be addressed by RRI actions

(R1) **Privacy and security concerns** raised by new applications that share data
(R2) Extensive **stakeholder engagement is too costly for a small company** like Spectro
(R3) Cleaning **contracts are awarded through tenders in which often much emphasis is on costs** of cleaning and with little attention for other values (including public hygiene)
(R4) **Social acceptance of innovation**: actors in value change do not necessarily see the need for improvement of current cleaning practices
(R5) **Company has only a small role in a long value chain**: The value chain contains many parties (the distributor, the user organization (e.g. hospital), parties within the user organization, the cleaning company etc). It is questionable whether it is feasible and desirable to aim at vertical integration along the value chain.

RRI approaches, tools, actions

Reflection & Anticipation:

(A1) **Stakeholder and value inventory**: a first inventory was made and then enriched on basis of A2 and A3.
(A2) **Literature study** about hygiene issues in hospitals and the potential for better cleaning solutions.
(A3) **Development of value scenarios**: these are short hypothetical stories about (unexpected) use that help to reveal relevant values and potential value conflicts.
(A4) **Inventory of conflicting values and ways to handle them**: these were based on A2 and A3 and put in a diagram to show the values that reinforce each other and that might be at tension in the development of the new product.

Inclusiveness:

(A5) Better inform customers about collection of data: based on the value scenarios (A3) it was decided that better informing customers would help to prevent some potential ethical issues. This resulted in T2.
(A6) **Stakeholder dialogue at the branch level**: a stakeholder dialogue at the branch level is chosen to overcome barrier R2.
(A7) Pilot study at a hospital.

Responsiveness:

(A8) **Investigate implications of GDPR**: The data that are currently collected are most likely not personal data in the sense of the GDPR (General Data Protection Regulation) of the EU because they cannot be traced back to individuals. Nevertheless, it would be wise for Spectro to develop a policy about privacy collection and sharing that explicitly addresses privacy issues, in particular because future technological innovations may involve the collection of data that can be traced to persons.
(A9) **Broaden CSR reporting to include ethics and values in innovation** as well

Roadmap design

The aspects relevant for the RRI uptake by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 4).
The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake.

The company's CEO has indicated that participation in the PRISMA project was particularly useful for him because it made him think about issues he would not normally think of. Spectro now aims at more actively sharing data with its customers so that they can take responsibility for the frequency and quality of cleaning. The CEO also found out that many of his customers are not aware of the data being collected and of the potential value of this data. He now sees it as the company's responsibility to make its customers more aware. Increased collection and sharing of data may also potentially raise privacy issues. The data that are currently collected are most likely not personal data because they cannot be traced back to individuals. Nevertheless, it would be wise for Spectro to develop a policy about privacy collection and sharing that explicitly addresses privacy issues, in particular because future technological innovations may involve the collection of data that can be traced to persons.

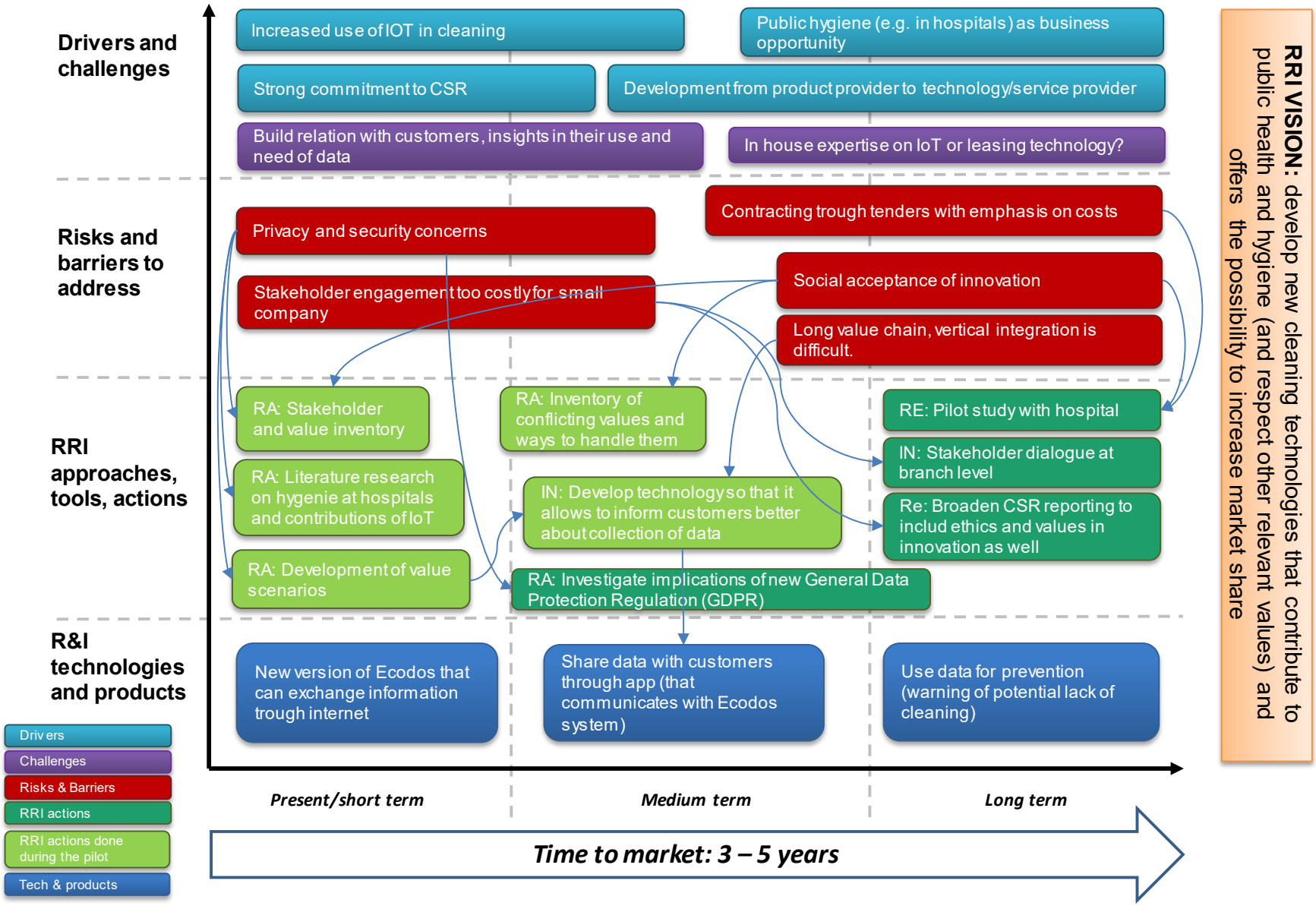

Figure 4 Spectro, PRISMA RRI roadmap

6. Aerialtronics

6.1. Case description

The Company

Aerialtronics develops autonomous Unmanned Aerial Vehicles (UAVs). UAVs, also known as drones, are large vehicles that can operate either autonomously or in a swarm. The company focuses on specific technologies that allow the drone to operate more independently from an operator and aims to sell the drones for professional and commercial tasks, such as monitoring and small maintenance tasks carried out for instance by police, fire departments or industrial inspection and maintenance companies. In the Autumn of 2017, the company was acquired by Drone Volt, a French manufacturer of commercial drones. With the acquisition of the knowledge base of Aerialtronics, Drone Volt can further develop the drone technology and include specific technologies, in particular in the field of security.

Central to the UAVs is the development of technologies allowing these vehicles to operate safely in an urbanized environment. Currently, existing legislation prevents these activities and as such the commercial value of the technology.

Commitment

- The RRI PRISMA pilot has been endorsed by the head of legal council and regulatory affairs
- Motivation for RRI: learn about new methods and approaches to identify the risks and uncertainties with respect to potential future ethical, legal and social impacts when developing and implementing commercial and professional drones. In the past, the company has faced serious pitfalls in the drone development as a result of ethical, legal and social issues which led to longer lead times, higher costs and endangered competitive position.

Context

- Type of pilot organization: SME
- Country: The Netherlands
- R&I project selected: PENSAR
- Technology: autonomous vehicles
- Relevant regulatory regimes: safety, security legislation, General Data Protection Regulation
- Type of R&I activities: in-house
- Type of business: business to business
- Time to Market (indicative): 1-3 years
- CSR policies: in-house corporate sustainability, privacy and dual-use ethical policy
- Gender policies in R&I: the company has no explicit policy in this respect, but given the field of operations it is relatively more men as compared to women who work in aerospace and electronics
- RRI Maturity Level: Tactical

Materiality and experimentation

- Key stakeholders: users and bystanders, authorities (e.g. police), civil aviation roads authorities, national Civil Aviation Authority, local municipalities, market clients and end-users such and inspection companies for off-shore and wind-turbines.

- Key ethical, legal and social issues: safety, security, privacy, data protection, data ownership (use of data and images that are produced by camera's), respect to the use of and the criteria for type of public and commercial drone operators

- RRI actions selected for the PRISMA pilots: stakeholder dialogue, ethical and social analysis

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the PENSAR project are [7]

    - Q1.4: Product quality; Q1.5: Product reliability;
    - Q2.1: Product acceptability; Q2.6: Address user's needs and rights' (e.g. privacy, data ownership, etc.); Q2.7: Trust with/avoid conflicts with business partners, suppliers and end-users
    - Q3.5: Building legitimacy and gain consumer loyalty on the product;
    - Q4.3: Address regulatory barriers; Q4.7: Avoid irresponsible behaviour
    - Q5.5: (favoured) access to financial support;
    - Q6.1: Direct costs to perform the RRI action

6.2. RRI Roadmap

RRI VISION

Develop drones with innovative active visual monitoring systems for application in public emergency and security, and industrial applications, ensuring safety, and safeguarding users' rights, including privacy and fair use of data.

RRI technologies and products

Aerialtronics has developed professional drones that are equipped with technology to monitor and survey by drawing on artificial intelligence and big data analytics. The main technology is the Altura Zenith surveillance system which can be extended by data capture modules (audio, video, physical parameters, etc.) and software for the processing and analysis of the data collected.

The technology we focus on in the PRISMA pilot is the PENSAR. The PENSAR is a dual spectrum computer vision platform that is mounted to a drone and operates with the Altura Zenith. The PENSAR can capture images and data and analyse it real-time by making use of reading text or thermal vision. This helps the operator of the drone, for instance to recognize characteristics, read license plates of cars or serial numbers of equipment immediately in the course of performing monitoring tasks.
PENSAR is equipped with a special privacy masking tool. This tool automatically and instantly blurs the details of sensitive data such as the privacy of bystanders.

We decided to focus on the PENSAR technology, because it is being sold and has a potential high intrusion on people's private life.

Drivers and challenges for RRI

Drivers

- Possible **areas of application for drones are continuously increasing**
- **Entry into new markets**, such as urban areas

Challenges

- **Industry fragmentation, absence of industry standards in technology**
- **Regulation needs evidence, public and media are receptive to the issues with drones**

[7] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

- **Regulation for emerging and novel, autonomous, AI data driven drone technologies**
- **High level discussions and international regulation authorities are difficult to access for SMEs**

Risks and barriers to be addressed by RRI actions

- **Small companies do not see their relevance** in the ethical discussion and acceptance of drones
- **Lack of space to conduct experiments no living labs for aerial drones, no evidence**
- **Regulatory compliance burden and costs for companies**, in particular SMEs
- **Limited applications leading to an elimination of potential clients**. Applications suitable only for those with certificate to fly
- Limited product acceptability, **reluctance to autonomous aerial drones due to privacy and safety**

RRI approaches, tools, actions

Reflection & Anticipation

- **Privacy and social impact analysis**: to ensure that the drones and the camera systems are used wisely by commercial operators, the technology is equipped with smart camera's that automatically blur faces of people and protect the disclosure of other private information. This technology is not fully certified and needs to be included in compliance and regulatory protocols. Within the pilot it has discussed within the company and with stakeholders how to generate data and evidence in order to build a case for regulatory authorities to accept the technology and allow operators to use it in their operations.

Inclusiveness

- **Building legitimacy, connecting stakeholders and industry partners**. Individual companies do need to see they have a role in the development of regulation. By building a community of producers and users of drones, bringing together their knowledge and concerns, the company tries to develop a playing field for discussion, and strengthen the legitimacy of the overall sector
- **User based and stakeholder inclusive approaches to experimental sites/living labs.** The development of living labs and test fields with stakeholders can help to conduct experiments and provide evidence that the new technology does respect ethical, legal and social issues.
- **Engage collaborations within industry to develop common interest, set standards**. To ensure the industry is committed to hold to the guidelines it necessitates the inclusion of various industry and policy experts and have them jointly collaborate by warranting their ownership and commitment.

Responsiveness

- **Development of design guidelines for regulatory compliance (safety and ethical requirements), in cooperation with regulators and authorities.** The aim is to provide a framework for companies in the drone industry to organise and have a common approach for drone development and operations which can also be easily checked and monitored by local and regional authorities.

Roadmap design

The aspects relevant for the RRI uptake by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 5).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake for Aerialtronics. It could be as well helpful for other companies in the field developing specific add-on technologies for drone applications, such as smart camera systems.

Aerialtronics is very active in the short-term activities, developing a framework of reference for drone design and development. The effect of these guidelines is aimed at the longer term to ensure acceptance between commercial drone operators and the governmental authorities.
The smallness of the company in terms of resources and representativeness, puts pressure on the extent the company can live up to meeting the steps as outlined in the roadmap. Yet the drone sector is characterised as an emerging one with many small players and Aerialtronics is, despite its small size, among the major leaders in the sector, and has a strong position in the stakeholder dialogues with governments at EU level to promote further regulation in the field.

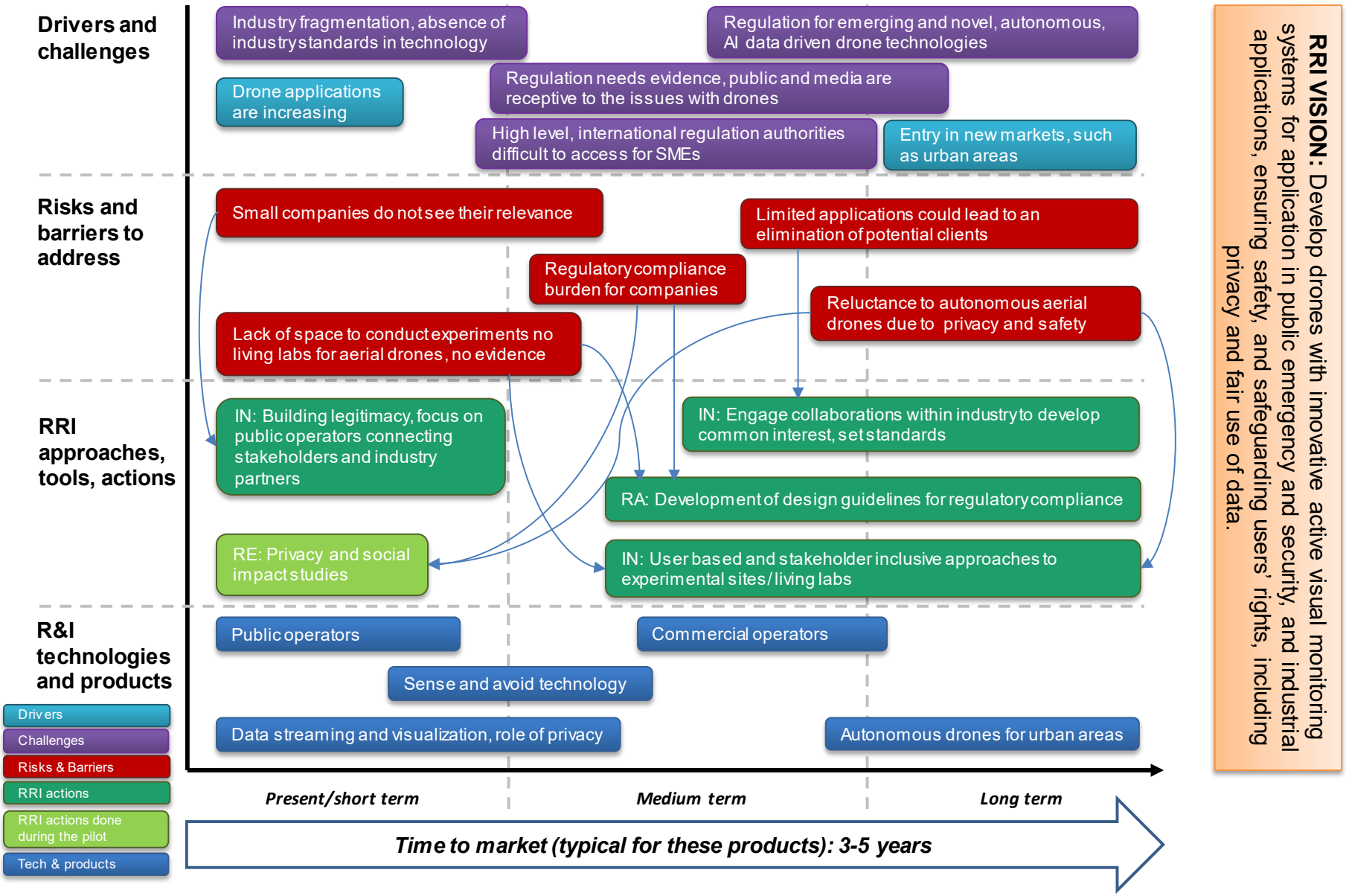

Figure 5 Aerialtronics, PRISMA RRI roadmap

7. Hub of all Things

7.1. Case description

The Company

The HAT ecosystem is the first-ever personal data exchange ecosystem that enables individuals and organisations to exchange data directly between individuals and organisations without third party involvement.
The HAT is therefore a personal data platform for firms to offer individuals services for their data in a scalable way, yet allowing individuals to control the data rights given to firms. Importantly, the HAT and its transformed data is owned by the individual. For firms, the HAT opens opportunities for exchanges and use of personal data in a way that is privacy preserving, real time and on demand.
The enterprise grows out of a series of university-based research projects. The HAT project as a whole has received several grants from the RCUK/EPSRC/digital economy fund.
Alongside the UK Government funded research projects, there are two central private organisations: the HAT Community Foundation (HCF) Ltd., a not for profit company governed by its membership on behalf of the whole HAT community and the HAT Data Exchange Ltd (Hatdex), a private limited company with share capital, with a mission as a social enterprise.

Commitment

- The RRI PRISMA pilot has been endorsed by both the founder and the Commercial Director of HAT
- Motivation for RRI: Better understanding of the ethical, legal and social impacts and uncertainties related to technology development, exploring ways to ensure societal acceptability of the final product.

Context

- Type of pilot organization: SME
- Country: UK
- R&I project selected: Hub of All Things
- Technology: Internet of Things
- Relevant regulatory regimes: General Data Protection Regulation
- Type of R&I activities: in-house and cooperative research, based on public -private partnership
- Type of business: business to business and business to consumers
- Time to Market (indicative): 1-3 years
- CSR policies: the work of HAT is sustained by the non-profit HAT Community Foundation, which represents HAT members, and defines ethical requirements that regulates the HAT personal data exchange ecosystem
- RRI Maturity Level: Strategic

Materiality & experimentation

- Key stakeholders: technology developers, certification bodies, consumers, companies, R&D partners (research centres and academia, business partners), public and private investors, market clients, society (media and the public)

- Key ethical, legal and social issues: information privacy, data ownership, commercial use of private data, respect of users' rights, transparency (of data collection), security

- RRI actions selected for the PRISMA pilots: embedded ethicist

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the HAT are [8]

    - Q1.1: Inspire technological innovation; Q1.5: Product reliability
    - Q2.1: Product acceptability; Q2.5: Product related services and guidance; Q2.6: Address user's needs and rights'
    - Q3.4: Customer satisfaction, meeting new consumers' needs or requests; Q3.5: Building legitimacy and gain consumer loyalty on the product;
    - Q4.3: Address regulatory barriers;
    - Q5.3: Market penetration; Q5.5: (favoured) access to financial support;

7.1. RRI Roadmap

RRI VISION

Develop distributed data platform as a mechanism for increased personal control of data

R&I Technologies and products

The 'Hub of All Things' is a secure internet platform for storing, donating, personal data, but without aggregating it. The HAT entails the HAT micro-server, which is a new technology that confers intellectual property rights of personal data to individuals through their ownership of a database, wrapped with containerised microservices. Firms can (1) build smart devices that individuals can control and acquire the data on the device onto their HAT; (2) build smart applications for individuals to make use of their data; or (3) help individuals exchange their data for better buying decisions, personalisation and recommendation (4) not need to hoard data as firms can request for data in real time and on demand whenever needed and only while the user is using the service.

Drivers and challenges for RRI

Drivers

- **Stricter regulation on privacy and data protection**
- **Demand for secure, safe and privacy preserving exchange of data across individuals and companies**
- **Need for global operating standards for personal data exchange**
- **Growing public reaction against non-distribution to account holders of value of their data**: there is a widespread complaint in public discourse concerning the unfair extraction of the value of personal data or the use of personal data without obtaining proper consent
- **More and more hacking of commercial and public sector and personal data**. Large data sets held by organisations of any size are vulnerable to the increasingly sophisticated methods deployed by hackers.

Challenges

- **Internet providers charging for use of internet services in exchange for loss of right to harvest and analyse data.** Widespread abandonment of the data-in-exchange-for-services model of the online economy and instead the use of straightforward paid models without the imperative to exploit personal datasets.

[8] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

Risks and barriers to be addressed by RRI actions

- **Scaling up use by individuals incentivizing firms with non-distributed data sets to set up new accounts on HAT, get existing users to migrate to HAT.** The HAT is only useful if it has a wide uptake; it is only likely to have a wide uptake if it is useful. The challenge that the organisation is working on is how to create a snowball effect that would lead to widespread uptake.
- **Identifying the Data controller: is it the HAT management, or commercial users of HAT who recruit customers via a HAT platform**. There remains a legal issue of who is to be assigned the status of Data Controller, and in particular whether the HAT organisation is to be assigned this status individual HAT users are their own Data Controllers. If one of the HAT organisations itself has this status, then there is a diminishment of its claims merely to be acting to facilitate people owning their own data
- **Converting HAT to a Data sale platform**: **Sales by individuals to aggregators, researchers**. The long -term goal is to create a platform that enables individuals to obtain the economic value of their personal data in accordance with their own preferences for privacy
- **Data protection legislation may create confusion over the adoptability of HAT as a response to hacking threats**. The HAT depends in part on the legal idea that an individual can own a database (even if individuals cannot own pieces of data). It remains to be seen in the context of evolving data protection legislation how that legal idea plays out.

RRI actions

Reflection & Anticipation

- **Ethical design of data auctions.** Technologists might reflect upon the various possible pricing models for how personal data is valued on exchange platform

Inclusiveness

- Create understanding among users about informed data donations in the HAT and learning form the community which are the needs and users' requirements about data protection or use. E.g. through **user-centered design and stakeholder dialogues.**

Responsiveness

- **Embedded ethicist**: translation of existing practices into RRI-terms
- **Privacy by design approach in HAT**: in order to make people sure that their data will be handled in the right way, incentivizing mass take up of the HAT by individuals
- Consider adoption of sustainability, and business ethics **certification schemes** to formally recognize RRI principles implemented by HAT, and as well showcase HAT as a social enterprise

Roadmap design

The aspects relevant for the uptake of RRI by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 6).
The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake. Implementation of RRI could help HAT to engage with the community of stakeholders, and make the people aware about the moral motivation of HAT project, in order to inform the development of the technology, and ensure HAT is representing as much as possible consumers and their interest, and thus gain their trust.

HAT is convinced that the digital economy is going to shift from a centralized to an individual model of control of personal data. In this scenario, an ethical approach toward personal data economy will be an essential factor to be a trustworthy business that engages with the consumer, and to gain a competitive advantage in the field. RRI is the way to explore and found solutions toward this scenario.

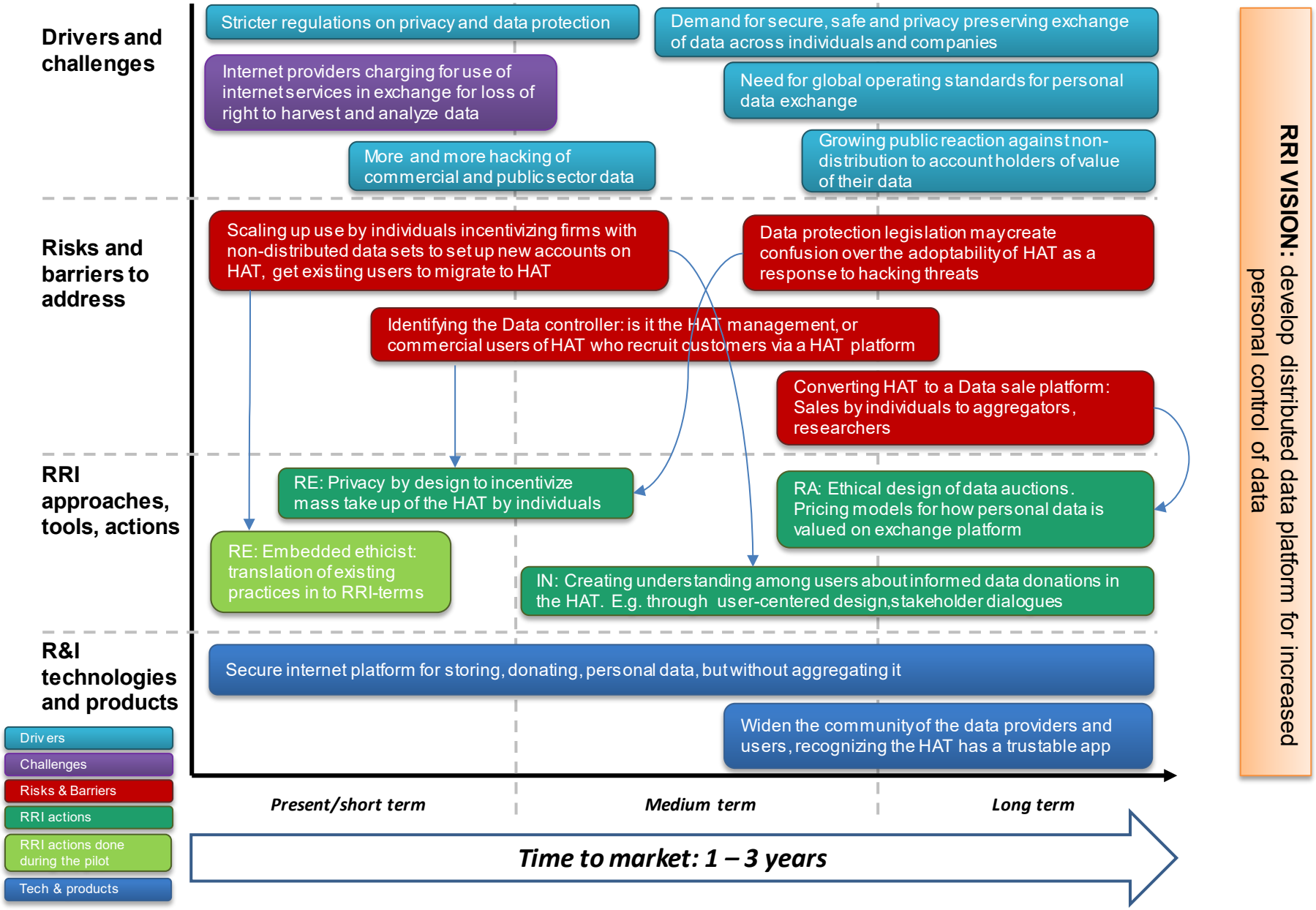

Figure 6 Hub of All Things, PRISMA RRI roadmap

8. RDM

8.1. Case description

The Company:

The RDM Group, produces small low-speed self-driving pods. These are envisioned as being deployed for the 'last mile' of a journey, such as between a railway station and the final destination. They also might be used in shopping malls, university campuses, airports, or for parcel delivery.
The company RDM is part of several consortia receiving funding from Innovate UK, a body that distributes government funds for research. Amongst the project members are also Jaguar Land Rover and Milton Keynes Council. Furthermore, RDM has been involved in UK research council funded projects on automated cars managed by Warwick Manufacturing Group, Warwick University, including the projects INTACT, SWARM, and SMARTER.

Commitment

- The RRI PRISMA pilot has been endorsed by the Chief Technical Officer
- Motivation for RRI: exploring ways to ensure societal acceptability of the final product: involve a diversity of stakeholders to discuss about how vehicles should be conducted, how the data collected should be used in order to respect people's rights and how autonomous vehicles could affect or improve the public spaces, urban planning or commerce.

Context, materiality and experimentation

- Type of pilot organization: SME
- Country: UK
- R&I project selected: self-driving pods
- Technology: Autonomous vehicles
- Relevant regulatory regimes: General Data Protection Regulation, safety, security, mobility and environmental regulation
- Type of R&I activities: in-house and cooperative research (public -private partnership)
- Type of business: business to business, business to consumer
- Time to Market (indicative): 3-5 years
- CSR policies: none explicit
- RRI Maturity Level: Tactical

Materiality & experimentation

- Key stakeholders: universities and other research partners, suppliers, commercial partners, local governments funders, local communities, and end-users of the pods (both private citizens and businesses), media and the general public
- Key ethical, legal and social issues: information privacy, commercial use of private data, and urban planning, safety of trials on public roads
- RRI actions selected for the PRISMA pilots: embedded ethicist

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the self-driving pods project are [9]

    - Q1.2: Feasibility of the technology solution; Q1.5: Product reliability
    - Q2.1: Product acceptability; Q2.2: Product safety;
    - Q3.4: Customer satisfaction, meeting new consumers' needs or requests; Q3.7: Fulfil ethical and social requirements
    - Q4.3: Address regulatory barriers; Q4.5: Risk management; Q4.7: Avoid irresponsible behaviour
    - Q5.3: Market penetration;

8.2. RRI Roadmap

RRI VISION

Developing automated and personalized public transport to reduce traffic, pollution and parking land use in urban areas. The vision is to develop this technology in a way that is:

- carried out in consort with all involved, especially its end users and those who live in the spaces in which it will be deployed
- both safe and inconspicuous, and tested rigorously
- proactively open, transparent and fair about its use of people's personal data
- demonstrably an improvement in sustainability terms

R&I Technologies and products

Electric Automated Cars for Public Transport: The core deployment of the technology is the automated vehicle for the purposes of public transport in a city.
Market for Retailers in Routes: Among the possible revenue models for the technology is the creation of a market among retailers for advertisements or even offers of different destinations to customers.
Smart sensors of real time traffic densities, transport demand: The technology includes a set of different sensors that can detect, predict, and avoid traffic congestion, with a set of driverless pods acting as an aggregated group.
Electric commercial vehicles for urban deliveries: Alongside the passenger carrying function is the possibility of deploying the vehicles for delivery of goods.
Urban pods as data collectors and transmitters: The pods must collect a great deal of data in order to function, and this is likely only to increase as data collection technology in general improves and gets cheaper.

Drivers and challenges for RRI

Drivers (technology)

- **Fixed business hours making for peaks and troughs in demand**: Transport in cities is subject to rush hours and quiet periods; in rush hours the infrastructure will be heavily stretched and there will therefore be great value in finding ways to reduce the demands upon it, for instance through the creation of the kind of park and ride scheme proposed by the RDM driverless technology.

[9] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

- **Multiplication of delivery technologies by large internet retailers**: The various proposed uses of the driverless pod include their use as a delivery channel for internet retail products. This is one of the several potentially lucrative uses of the technology.

Challenges

- **Difficulties of automated transport off motorways:** It is challenging to deploy automated vehicles — even slow-moving ones — in complex residential environments that include cyclists, pedestrians, and larger vehicles. Success will depend on robust technological solutions to the various problems raised.
- **Oversight about data collection**: RDM projects is designed on the model of service in exchange of data" – raising revenue by brokering the data provided by users – so users need transparent information about the data collected and used, in order to provide informed consent. Transparency also avoids a possible uses of users' data beyond the individual's expectations.
- **Transparency in communication with users:** road-users need to be informed about the behavior of autonomous vehicles

Risks and barriers to be addressed by RRI actions

- **Public misapprehensions about safety and risks**: alongside technological robustness, in order to succeed it will be necessary to take the correct path being with regard to popular attitudes towards the technology
- **Crowding of pedestrian spaces by delivery vehicles:** If the vehicles are perceived as crowding pedestrian spaces, especially where they are in a delivery function, then public uptake will be diminished
- **Resistance to vehicle sharing:** In order for the efficiency with regards to reducing congestion, it will be necessary for the vehicles to operate with a ridesharing function. It remains to be seen how far there is a market for this product that sits in between public transport, on one hand, and private cars and taxis on the other.
- **Protocols for data exchange with authorities**

RRI approaches, tools, actions

Anticipation & Reflection

- **Advanced Simulation and Testing of Speeds, environments**, also based on stakeholder engagement: in order to anticipate and characterize possible risks or conflictual situations. This will improve the risk management and safety procedures and will highlight the conflicts in order to solve them.

Inclusiveness

- **Co-creation with retailers, urban transport authorities, local residents** in order to involve who has a stake in the definition of the urban planning and to improve the positive social impacts of the project. The users could be interested in a service providing them information about places, to find shops with specific characteristics, or receive advertising based on their preferences.

Responsiveness

- **Embedded ethicist:** translation of existing practices into RRI-terms
- **Environmental impact studies**: in order to select the best options for the development of autonomous electric vehicles usage and for environmental impact reduction (e.g. aiming at the maximum traffic reduction)

- **Oversight and transparency about data collection**, including use of specific ethical protocols to guarantee respect of users' rights

Roadmap design

The aspects relevant for the uptake of RRI by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 7).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake. The PRISMA experience has been really informative for RDM, it allowed a small family business –with limited formal education in ethics or responsible innovation – to benchmark itself against the rest of the innovation world, have a better understanding of the values, needs and concerns of its customers, finally improving the product.

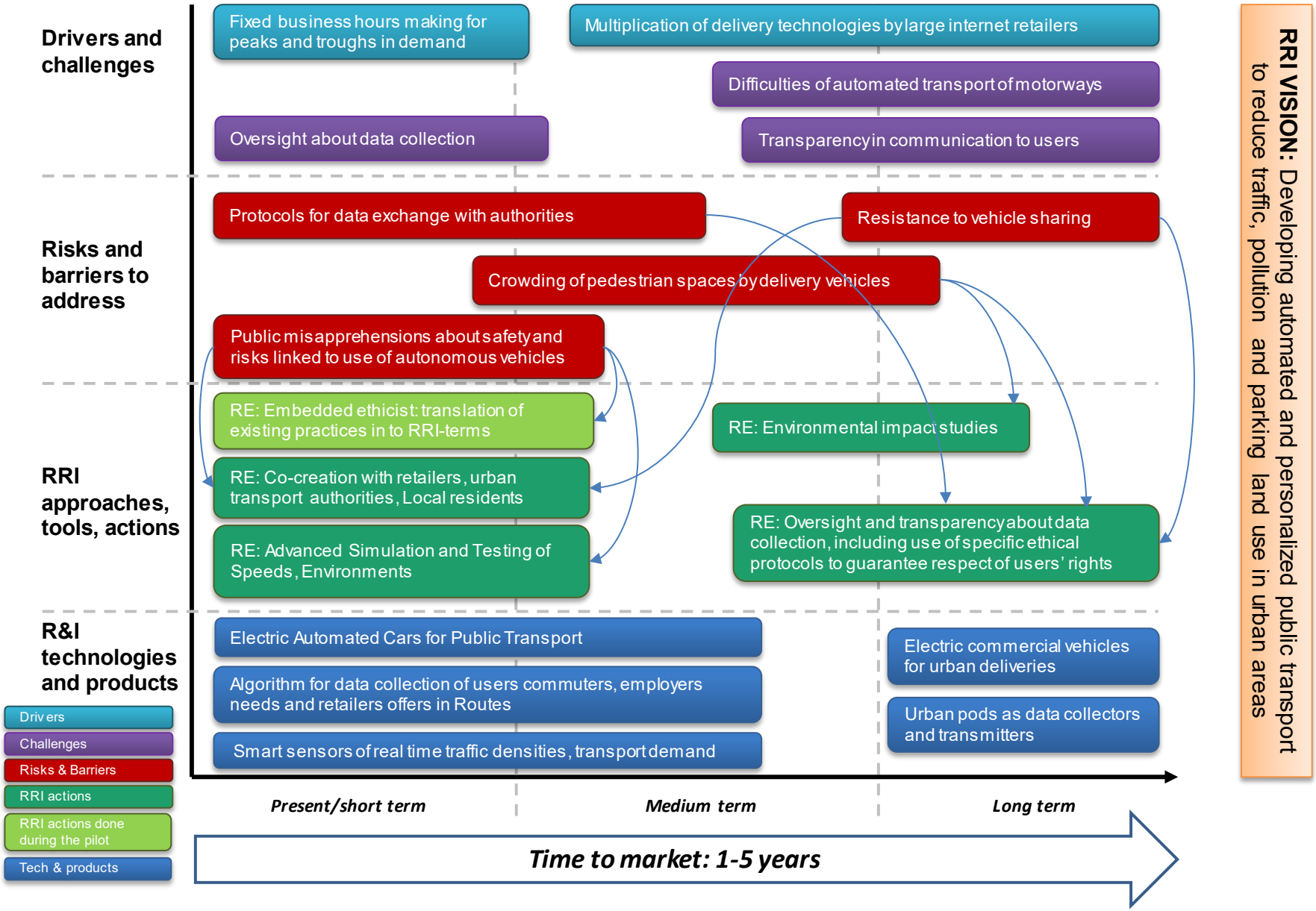

Figure 7 RDM, PRISMA RRI roadmap

9. BISIGODOS

9.1. Case description

The Company

The EU project BISIGODOS aimed to identify ways to use algae as a feedstock in order to produce valuable chemicals, amino acids and high added-value bio-resins that would normally be produced using petrochemicals. The algae biomass can be fed directly with CO_2 from industrial emissions (cement, steel factory, thermal power plants, etc.) as a raw material that is cost-effective and renewable. The process is assisted by solar radiation, nutrients and sea water microalgae. The consortium brought together expertise and resources within the areas of: microalgae and photo-bioreactors production and optimization, manufacture of amino acids for food products, production of conductive polymer coatings, bio-resin development for water-based inks, bio-surfactants production and bio-PU adhesives manufacturing, and end-users in the food, flexible packaging, hair care, metal industry and paints products.

This PRISMA pilot has a different approach compared to the other pilots. The work has been retrospective, looking and analyzing from an RRI perspective activities and results of the EU project BISIGODOS. The work will be informative for the development of future initiatives of partners, and as well as setting research calls in this field, especially within the EU science funding context.

RRI commitment

- The RRI PRISMA pilot has been endorsed by the project coordinator and the project partners
- Motivation for RRI: better understanding of the ethical, social and legal issues and stakeholder expectations the technology faces; and better alignment for future bids for research funding

Context

- Type of pilot organization: public-private partnership (EU funded research project)
- Country: UK
- R&I project selected:
- Technology: industrial biotechnologies
- Regulatory regimes relevant for the R&I project: IPR protection frameworks
- Type of R&I activities: cooperative research
- Type of business: business to business
- Time to Market (indicative): not applicable
- RRI Maturity Level: Defensive

Materiality & experimentation

- Key stakeholders: research organizations, companies involved in chemicals, adhesives, coatings, ink, surfactants, food, consumer groups, other industry actors, investors, policy makers, media and the public, companies involved in the end-of-waste and recycling sector
- Key ethical, legal and social issues: profit and short/long term research vs improvement of environmental and social and economic impact, issues of cooperation amongst partners, Intellectual property rights aspects, transparency
- RRI actions selected for the PRISMA pilots: embedded ethicist

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the Bisigodos project are [10]

    - Q1.2: Feasibility of the technology solution; Q1.4: Product quality;
    - Q2.3: Product environmental sustainability; Q2.7: Trust with/avoid conflicts with business partners, suppliers and end-users
    - Q3.7: Fulfil ethical and social requirements (e.g. for access to funding)
    - Q4.2: Team cooperation and motivation for product development; Q4.3: Address regulatory barrier
    - Q5.1: Product cost; Q5.2: Time to market;
    - Q6: RRI action costs: Direct costs to perform the RRI action

9.2. RRI Roadmap

RRI VISION:

Developing bio-based (algae) feedstock to replace petrol-chemicals feedstocks, based on RRI-aware Life Cycle Analysis and funding calls more specific on RRI demands: the vision is to ensure future projects on developing algal oil products would carry out richer Life Cycle Assessments that draw more widely on the range of LCA methods that are available, including greater input from external stakeholders.
Furthermore, it is envisaged that funding calls in this area will provide guidance for applicants on the RRI tools that they are expected to deploy, or attainments that they are expected to achieve.

R&I Technologies and products

The five products developed on the project using algal oil were: adhesives, coatings, ink, surfactants, food. In the future, the project partners would aim at the general replacement of petrochemical feedstock with algae feedstock for consumer and industrial products

Drivers and challenges for RRI

- **Consumer products produced without using petrochemicals, Lower resource usage, absorption of Co2.** The project aimed at developing ways to use algae in order to produce materials that would normally have a petrochemical basis. Aside from the advantages of moving away from petrochemical feedstocks in terms of sustainability and geopolitics, the methods developed in the project ultimately sought ways of making products that not only had a lower resource impact themselves but also would absorb the carbon dioxide emissions of other industries.
- **High-value consumer products.** The project focused on creating products that have high economic value such as life-style foodstuffs and toiletries. Such a focus is more likely drive the technology in the future, since the possibility of a profit is more likely to become real.

Risks and barriers to be addressed by RRI actions

- **Early stage technology cannot achieve economies of scale.** As with any new technology development, the relatively small-scale production that took place in the project was unlikely to show economic viability in comparison to existing industrial methods. The life cycle and economic assessments carried out at the end of the project confirmed this.
- **Uncertainty about market or viability.** Since the pure resource case for the products can't be made at this stage, those developing them must depend on the analysis changing in the future. This may be through inherent improvements in the techniques themselves, newly discovered economies of

[10] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

scale (perhaps in the production of algae), or in changes in the petrochemical markets, perhaps due limitations on the supply of crude oil or new governance structures favouring non-petrochemical methods.

- **Commercial imperative of partners.** The specifications for the products to be produced were made and controlled by the commercial partners on the project. While this had the advantage of ensuring that the project focused on producing products that may ultimately go to market, it had the disadvantage that only a relatively narrow range of stakeholders were involved at the coal face of deciding what the focus of production would be.
- **Experimental nature of project.** Not all of the products were possible to make as expected; the technology remains at a relatively early stage. It is therefore greatly aided by the university setting and the investment of outside funds.

RRI actions

Reflection & Anticipation

- **(Retrospectively) embedded ethicist:** The embedded ethicist approach was applied retrospectively in order to identify and analyse the ethical issues that arose, trying to extrapolate lessons for future similar projects. Such projects would benefit from the direct deployment of the embedded ethicist approach.
- **Implement Life Cycle Assessment, value assessment and social LCA:** The project involved a Life Cycle Assessment and a Value Assessment. From an RRI perspective this might be improved through making assessments that are anticipatory rather than merely retrospective, are stakeholder engaged, open access, and have explicitly socially-led goals and scope. Moreover, the assessment was carried out on the assumption that each product (surfactants, coatings, and so on) would be separately produced; it would be worthwhile also to see such assessments on the wider assumption that algal oils replaced petrochemical feedstocks in the economy more broadly.
- **Anticipatory' assessments of technology,** to take into account economic or social value and indeed to draw out the values that are implicit in those carrying out the research

Inclusiveness

- **Stakeholder engagement: work with research, business and social actors sharing values and create positive ethical networks.** Involve both internal stakeholders (e.g. corporate partners in project) and those outside of the technology with expertise on possible economic effects of deployment.

Responsiveness

- **Implement user-centered design, user innovation, flexible and adaptive design, co-creation approaches**, involvement from the outset a wide range of stakeholders
- Performing LCA and S-LCA starting from the very early stages of design, considering the large part of environmental impact is locked in the design stage.

Roadmap design

The aspects relevant for the uptake of RRI by the company have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 8).

The BISIGODOS pilot in PRISMA has been retrospective, looking at a project already finished. The recommendations and actions included in the roadmap could help to shape future calls in the field or could help research actors to find the best ways to implement RRI aspects in future projects.

The roadmap helps in understanding the value that RRI implementation could bring into product development. In future calls and projects, it will be essential to be more explicit about the actions needed to meet societal needs and expectations, in terms of stakeholder engagement, assessment of social, environmental, economic benefits or other aspects. And this is exactly what the action plan of the roadmap allows to do.

However, RRI implementation requires extra costs in product development, and therefore it is really important that addressing RRI aspects will become a requirement in future calls. This is the only way to ensure RRI implementation.

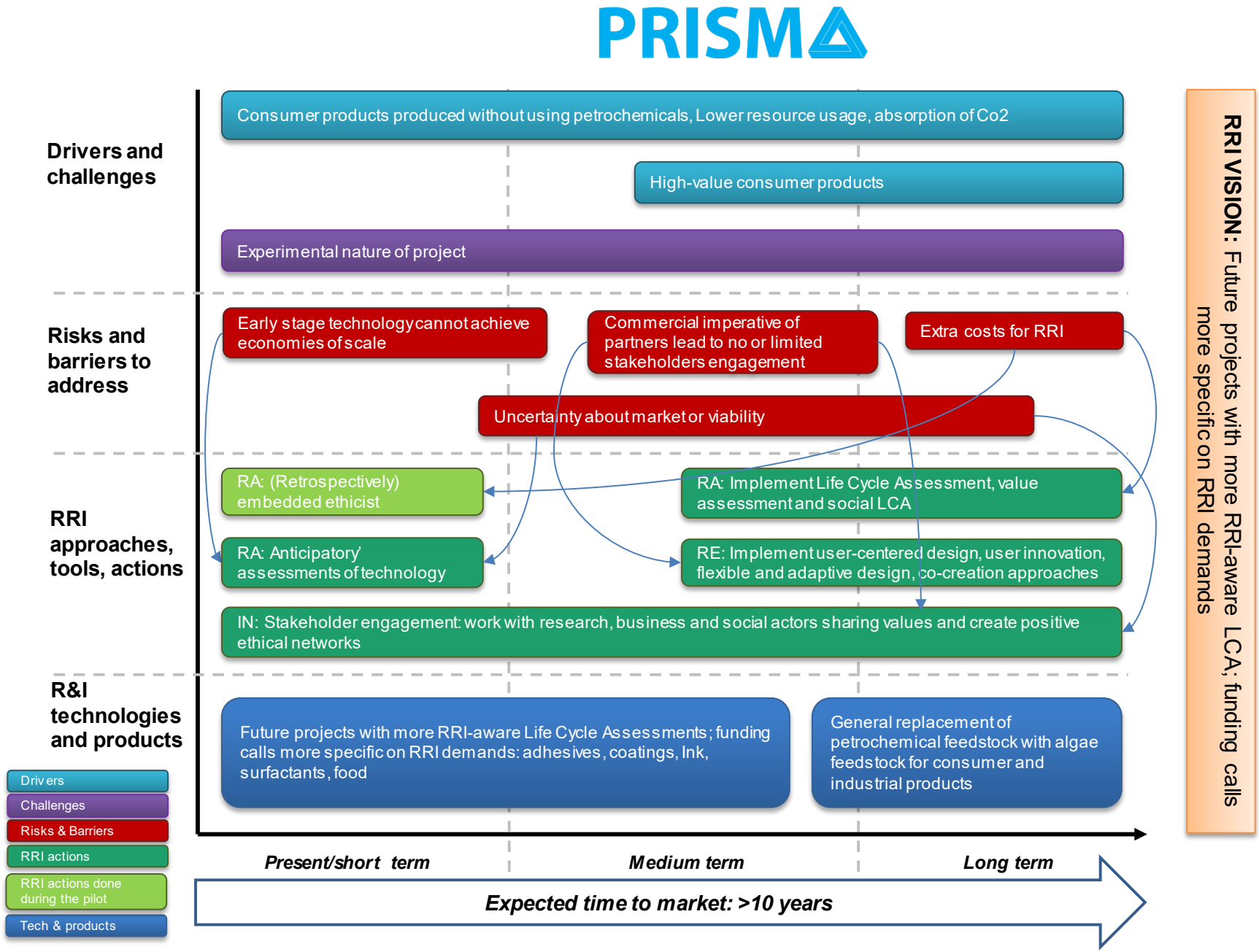

Figure 8 BISIGODOS, PRISMA RRI Roadmap

PRISMA

www.rri-prisma.eu