A Roadmap for the RRI uptake in the industrial context: a tool for strategy setting and RRI impact evaluation

Daniela Pimponi, Andrea Porcari,

Elisabetta Borsella, Pim Klaassen, Maria João Maia, Emad Yagmaei, Elvio Mantovani
About us

Airi – Italian Association for Industrial Research

• Established: 1974
• More than 80 members active in R&S (large companies, SMEs, public research)
• Key theme of action: R&I policies, KETs, RRI and sustainability

Mission
Promote industrial research and innovation as instruments to improve Italy competitiveness
Agenda

• Introduction to the PRISMA project

• Why RRI in industry

• Exploring the CEN CWA road-mapping process

• Case Studies
The PRISMA project
The Prisma project (2016-2019)

- Evidence on how RRI can **improve the innovation process**
- Integration of **RRI in the R&I and the CSR policies of 8 companies** active in the field of transformative technologies
- **CSR/RRI Prisma exemplar roadmap**, based on the 8 pilots roadmaps, that helps industries to implement RRI

Transformative Technologies (TT):
Transform production and **change the relation of the company with users, suppliers and stakeholders**. Contribute to a sustainable society and to competitiveness of Europe
The project workplan

1. Preparation of **RRI pilots**
   - Sep 2016 - Jan 2017

2. **Implementation** of pilots
   - Jan 2017 - Sep 2018

3. **Assessment and comparative analysis** of pilots
   - Jan 2017 - Sep 2018

4. Five **Stakeholder dialogues** across pilots themes
   - Apr 2017 - Dec 2018

5. **RRI-CSR Roadmapping process**, based on pilots roadmaps
   - Oct 2018 - Jan 2019

6. **Dissemination & exploitation**
   - Sep 2016 - Jul 2019

[Logos and Funded by the European Union badges]
Prisma pilots

Nanotech
- COLOROBBIA: Advanced medical therapies for cancer diseases
- LABORATORI ARCHA: Safer and more effective dermo-cosmetics

Biotech & Syn Bio
- EVOLVA: Sustainable production of synthetic agarwood products
- BISIGODOS: Sustainable packaging, coatings from waste algae biorefineries

IoT
- HAT: IoT distributed data platform for increased personal control of data
- SPECTRO: IoT in cleaning, to improve public health and hygiene

Automated vehicles
- RDM: Automated vehicles to reduce traffic, pollution, land use
- AERIALTRONICS: Drones, artificial intelligence and IoT solutions toward for safe, and acceptable use of drones in cities
A Roadmap for RRI in industry.

Why?
CSR & RRI: Business practices to address ethical and social impacts

- Corporate social responsibility
- Integrated reporting
- Social life-cycle assessment (S-LCA)
- Corporate Shared Value (CSV)
- Sustainability practices
- Business ethic,
- corporate social performance
- corporate citizenship...

- and risk, quality management

BUT, still little attention for research, innovation and product development
Mind the Gap
A management system

PRISMA developed a management system for RRI implementation:

- aligned with the ISO High Level Structure for management systems (e.g. ISO 9001)
- built on experiences on social responsibility, risk and innovation management (ISO26000, ISO 31000, ISO 56000)
- Looking at the whole R&I value chain

RRI has to be easy to be implemented by companies.

Easier to be integrated with existing procedures

Principles and terminology already known by companies

Involving specific company functions
CEN guidelines to innovate responsibly

CEN CWA 105: Guidelines to develop long-term strategies (roadmaps) to innovate responsibly

**Scope:** 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 and to improve the ethical and social impacts of final marketable outcomes.

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

The first EU standard document on RRI

The CEN CWA 105 – normative references

• Based on ISO and CEN Management standards on quality, CSR, innovation management, including;
  • High Level Structure (HLS) for Management systems, ISO/IEC Directives, 2015
  • ISO 26000 Guidance on social responsibility
  • ISO 31000 Risk management – Guidelines
  • EN ISO 9001 Quality management systems – Requirements
  • Series CEN/TS 16555 Innovation Management

Structure of the document, terminology and some procedures in common with these standards
CEN CWA: Terminology and definitions

Responsible Research and Innovation

✓ 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.

CEN CWA terminology and definitions:

Transformative/enabling technologies

- Knowledge, capital-intensive tech
- Systemic relevance for all phases of product development
- Pervasive, enabling process, innovation throughout the economy
- High R&D
- Rapid and integrated innovation cycles
- Highly skilled employment
- Multidisciplinary, trans-sectoral
- Trend towards convergence, tech integration

AND capacity to improve people’s health, safety and security, supporting sustainable development and secure connectivity and communication among systems and individuals
Why a roadmap for RRI in Industry?

When developing new products, especially coming from enabling technologies, there is an increasing need to:

- Address the increasing complexity of the innovation eco-system and of the societal demand
- Anticipate uncertainties (unknown), about technological, ethical, social, legal, safety, environmental, economical aspects
- Respond and react to actual (and unexpected) impacts of innovation

Early engagement of stakeholders is paramount
## Key benefits and drivers for the uptake of RRI on product development

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefits</th>
</tr>
</thead>
</table>
| Scientific & Technical  | • Inspire technological innovation  
                         | • Product quality                                                       |
| Ethical & Societal      | • Product acceptability, safety  
                         | • Product related services and guidance (e.g. ethics)  
                         | • Users’ needs and rights                                               |
| Strategic               | • Corporate image  
                         | • Build legitimacy  
                         | • Identify new market needs                                            |
| Organizational          | • Address regulatory barriers  
                         | • Risk management  
                         | • Avoid irresponsible behaviour                                         |
| Economic                | • Favored access to financial support                                   |
### Possible barriers for the uptake of RRI on product development

<table>
<thead>
<tr>
<th>Category</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific &amp; Technical</td>
<td>none</td>
</tr>
<tr>
<td>Ethical &amp; Societal</td>
<td>• Polarization of debate</td>
</tr>
<tr>
<td>Strategic</td>
<td>• Allocation and deployment of resources</td>
</tr>
<tr>
<td></td>
<td>• Limited awareness and skills</td>
</tr>
<tr>
<td></td>
<td>• Intellectual Property Rights</td>
</tr>
<tr>
<td>Organizational</td>
<td>• Allocation and deployment of resources</td>
</tr>
<tr>
<td></td>
<td>• Additional bureaucratic burden</td>
</tr>
<tr>
<td></td>
<td>• Lack of awareness and skills</td>
</tr>
<tr>
<td></td>
<td>• Lack of integration of RRI across the company functions</td>
</tr>
<tr>
<td>Economic</td>
<td>• Product cost</td>
</tr>
<tr>
<td></td>
<td>• Time to market</td>
</tr>
<tr>
<td></td>
<td>• Use of human resources</td>
</tr>
<tr>
<td>RRI action costs</td>
<td>• Direct costs to perform RRI actions</td>
</tr>
</tbody>
</table>
Testimonials from companies

**Interview with Giovanni Baldi**  
Director, C.E.Ri.Col. – Colorobby Consulting Research Centre

The videos below concern interviews with Giovanni Baldi (Director Research Centre).

> “We consider pivotal to our R&D efforts an open and continuous dialogue with stakeholders, patients, in the first place, and regulators, health-care professionals, policy makers, media, the society at large. It is vital to improve functionalities, quality and reliability, acceptability, of the NanoMed technologies and products. With PRISMA we learned the importance of focusing on the ethical and social impacts of NanoMed since the early phases of the development, to become responsive and trustworthy toward needs and requests from users and society. This experience has convinced us of the strategic value of RRI for NanoMed and our organization.”

**Interviews with Simon Brewerton, CTO of RDM**

These interviews are about 2 issues:
- Safety
- Ethical issues and stakeholder engagement

> ‘As part of our project work that we’ve done with the PRISMA project, we’ve been audited effectively against certain criteria that were generated from the PRISMA project, to see how responsible our innovation is at RDM’

**Interview with Stuart Coles, Warwick Manufacturing Group**

**Interview with Xiao Ma, HAT Data Exchange Ltd. Founder**

‘Once we started working with the Prisma community we found we’re not alone, we realized there’s a whole school of people who are doing similar approach as we do, we’re also learning from the community on different ways and in best practices of implementing ethical research and innovation.

Xiao Ma, HAT Data Exchange Ltd. Founder and Warwick University Senior Fellow’

**Interview with Timothy van Langeveld, Head Legal Council & Regulatory Affairs**

‘I think the main lesson that we have learned from the pilot is you can’t innovate in a vacuum. We have tried to do it for some time but you need others. You get the best results when you involve others’

**Interview with Laurens Metternich, CEO Spectro**

> ‘What was particularly illuminating for me was that by collecting more data about cleaning we also as company may get new responsibilities which may lead to new moral dilemmas. This has led us to adopt new policies for what data we share with our clients’

**Interview with Stephan Herrera, VP Evolva**

> ‘This program really allowed us to join a community of academic, government industry and friends who are all committed to RRI’

---

Funded by the European Union
Testimonials from companies

Collecting more data about cleaning may get new responsibilities which may lead to new moral dilemma..

The main lesson that we have learned from the pilot is you can’t innovate in a vacuum..

We consider pivotal in our R&D an open and continuous dialogue with stakeholders, patients, regulators, health care professionals, policy makers, media...

With PRISMA we learned the importance of ethical and social impacts...
Highlights on RRI uptake experience

- **Work to introduce culture changes in the organization**
  - Commitment of the management (R&D, company level)
  - Look for Return on investment, at least in the medium/long term (for company and stakeholders)

- **Need for tailored methods and approaches**
  - Understand the context, governance and decision-processes of the company
  - RRI interlinked with economical, technical aspects of product development
  - ad hoc «RRI» tools inspire, but (generally) do not fit. Integration of RRI in existing CSR and quality tools seems more promising

The CEN CWA propose an expert-driven, case by case, company specific approach to RRI uptake, to deal with differences across sectors, companies, and tech
https://www.youtube.com/watch?v=GScPbTh_x1I
The 6 steps of PRISMA Roadmapping process
The six steps of the RRI Roadmap

PRISMA propose a case by case, expert-driven and company specific approach to RRI uptake, to deal with differences across sectors, companies, and tech
Principles and actions for RRI implementation

- **Reflection & Anticipation**: Integrate analysis of ethical, legal and social impacts 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 actions are considered by the CEN CWA as minimum requirements for RRI uptake at company level.
# The six steps of the Roadmap

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOP MANAGEMENT COMMITTMENT AND LEADERSHIP</strong></td>
<td>Ensure endorsement of the organization toward RRI values and approach</td>
</tr>
<tr>
<td><strong>CONTEXT ANALYSIS</strong></td>
<td>Analyze the organization, the R&amp;I product(s) and technologies on which to focus; Identify ethical, social and legal impacts of the product and stakeholders of the product innovation eco-system</td>
</tr>
<tr>
<td><strong>MATERIALITY</strong></td>
<td>Identify and prioritize: drivers and challenges for RRI; risks and barriers to overcome; stakeholders to work with; significant RRI actions to pursue</td>
</tr>
<tr>
<td><strong>EXPERIMENT &amp; ENGAGE</strong></td>
<td>Perform exploratory/pilot RRI actions, engaging with stakeholders to inform the RRI roadmap</td>
</tr>
<tr>
<td><strong>VALIDATE</strong></td>
<td>Evaluate impact of the roadmap on both the product development and the organization (Key Performance Indicators)</td>
</tr>
<tr>
<td><strong>ROADMAP DESIGN</strong></td>
<td>Consolidate and visualize the long-term RRI strategy, covering all the R&amp;I value chain (time to market) and product life-cycle</td>
</tr>
</tbody>
</table>
Step 1

Commitment and leadership
Endorsement of the top management toward RRI values and approach

CHALLENGE: Integrate RRI in the culture of the organization

TASKS
➢ RRI roadmap, actions, objectives shared at the top level and in line with values, identity and stakeholders of the organization
➢ RRI principles integrated into the organization’s management systems and governance
➢ resources available for both the roadmap design and its future implementation
➢ Setting of an initial RRI vision

TOOLS: Internal reflection and advice by experts
Step 2

Context analysis
**TASKS:** (to identify)
- The tech and products, on which to focus on the RRI roadmap design
- The development phases of the RRI product (until the time to market or life cycle)
- The potential ethical, legal and societal impacts of the RRI product
- Mapping of stakeholders along the innovation eco-system, including an initial understanding of their needs and perspectives

**TOOLS:** Analysis of internal and external factors influencing the product development (e.g. SWOT, PESTLE - political, economic, socio-cultural and technological, legal and environmental factors), questionnaires

**CHALLENGE:** RRI implementation is strictly context dependent.
Example of a questionnaire to start the context analysis

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

**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
- personnel: age, education, sex, home country, race
- R&I & 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
Step 3

Materiality analysis
**Selecting significant impacts, RRI actions and stakeholders**

**CHALLENGE:** understand and anticipate significant values and impacts early on in the R&I value chain, to have time to change and adapt the process

**TASKS:** (to select)
- Drivers (creation of value, positive impacts), and challenges (for achieving the impacts) to realize the RRI products
- Risks and barriers to achieve the impacts. Consider scientific, technical, strategical, organizational, economic, ethical and social aspects
- Stakeholders of the RRI product to engage with
- Significant RRI actions to achieve impacts and address risks and barriers
- Vision of the roadmap, addressing drivers and challenges

**TOOLS:** Materiality matrix, interest/influence grid, ring stakeholder map, etc.
Example: materiality matrix

A way to analyze and prioritize issues emerged from the context analysis.

- **Material issues**: Issues critical to the success of the business strategy and stakeholders of the company.
- **Relevant issues, but not strategically material**: Issues relevant to both performance and stakeholders, but not central to the business strategy.
- **Non-material issues**: Low priority. These issues do not require special attention at this time. It is necessary to continue monitoring them properly to understand their future development.
Example: mapping of stakeholders of the innovation eco-system

A way to highlight connections between stakeholders, their roles in the innovation ecosystem and their possible contribution, for example in a co-creation process.
Step 4

Experiment & Engage
Perform pilot RRI actions, engaging with stakeholders to inform the RRI roadmap

**CHALLENGE**: create a dialogue with stakeholders, experiment RRI, and go out of your «comfort zone»

**TASKS** (select):
- Engaging key stakeholders of the innovation eco-system to review significant (ethical, social, legal) impacts
- Review the initial RRI roadmap with stakeholders
- Possibly perform additional RRI actions, to pilot activities planned in the roadmap
- Finalize the materiality analysis and consolidate the roadmap

**TOOLS**: focus groups, plenary sessions, multi-stakeholder workshops, world-café, etc.

*Avoid initiatives only to inform product development, studying people’s behaviour, product testing*
**Reflection and Anticipation**

- Ethical analysis (foresight, scenario analysis, social phenomena and trends evaluation, etc).
- Design for values, safe by design
- Meetings with R&D staff to reflect on
- Advice from experts on ELSI, on a need basis
- Life Cycle Assessment (LCA) and Social-LCA

**Inclusiveness**

- Sharing values and create positive ethical networks with businesses and social SHs
- Co-design with policy/normative actors
- Public dialogues (defining needs and concerns)
- Providing consumers an official role in the innovation process
- Capacity building with vulnerable stakeholders

**Responsiveness**

- User-centered design, co-creation
- Procedures for investigating reports of concerns or misconduct
- Adaptive risk management
- Embedded ethicists
- Ethical and FAIR research data management
- Include ELSI of R&I in CSR reporting
Step 5

Validate
Evaluate impact and feasibility of the roadmap on both the product development and the organization

**CHALLENGE:** evaluate both tangible and intangible, short and long term impacts of RRI

**TASKS** (select):
- Identify and select criteria, KPIs, and methods to perform evaluation of impacts
- Evaluate impacts of the RRI roadmap actions on
  - Product development, using lines of evidence (costs & benefits)
  - Organization, using Key Performance Indicators
- Resources and processes to operationalize the RRI roadmap: People, Time, Knowledge, Finance, Infrastructures
- Integration in the innovation, risk, quality, social responsibility policies of the organization.
- Documented information on the RRI roadmap

**TOOLS:** Multi Criteria Decision Analysis, qualitative and quantitative KPIs
Example: impact criteria and KPIs for RRI

Lines of Evidence
1. Scientific & Technological
2. Ethical & Societal
3. Strategic
4. Organizational
5. Economic
6. RRI costs

Key Performance Indicators
1. Awareness of moral values
2. Awareness of ethical issues
3. Does the company embed moral values in its innovations?
4. Does the company (actively) anticipate social effects of R&I?
5. Stakeholder engagement
6. Gender Diversity
7. Transparency and accountability about RRI-relevant choices
8. Learning mechanisms to address public and social values
9. Capacity to align to societal goals
10. Active monitoring of RRI impacts
Step 6

Roadmap design
Consolidate and visualize the long-term RRI strategy

- Commitment
- Context & materiality
- Materiality, experiment & engage
- Context

RRI VISION: Ensure societal acceptability/desirability

Drivers and Challenges to pursue societal impacts in product development

Risk and Barriers to be addressed by RRI actions

RRI approaches, tools, actions to ensure alignment of R&I products with societal needs

R&I Technologies and products (and milestones to reach the market)

Present/short term  |  Medium term  |  Long term

Time to market (or life cycle) of the R&I product

[Logos: Airi, PRISMA, FIT4RRI]
Consolidate and visualize the long-term RRI strategy

- The starting point is the long-term RRI vision
- Integration of ethical and social aspects with scientific, technical, strategical, organizational, economic factors
- At least one specific action for each of the RRI three key principles
- The construction of the roadmap is a flexible and adaptable process using a modular approach
Case studies
Examples: RRI visions of the pilots

- **COLOROBBA**: personalized and point of care therapy, for a highly effective, accessible and affordable treatments of severe diseases

- **ARCHA**: nano-based dermo-cosmetics products, based on ethically acceptable and sustainable production methods and safe and more effective use of natural and organic ingredients

- **EVLQVA**: Create a mutual understanding of a desirable innovation pathway that can benefit both the synthetic biotechnology value chain and stakeholders

- **BISGODOS**: bio-based (algae) feedstock to replace petrol-chemicals, based on RRI-aware LCA

- **HAT**: distributed data platform as a mechanism for increased personal control of data

- **SPECTRO**: new cleaning technologies that contribute to public health and hygiene (and respect other relevant values) and to increase market share

- **AERIALTRONICS**: drones, combine data collection and AI, ensuring safety, and safeguarding users’ rights, including privacy and fair use of data.

- **RDM**: automated and personalized public transport to reduce traffic, pollution and parking land use
A pilot example: the NANOMED project

RRI vision:
Realize a personalized, patient-centric and point of care therapy, for a highly effective, accessible and affordable treatments of severe diseases
NANOMED Project: timeline for development

Line 1: theranostic and cellular therapy approach: Proof of concept and testing

Line 2: Medical device for point of care treatment: proof of concept and testing

Line 3: Theranostic: Authorization, clinical trials and product development

Line 4: Cellular therapy and point of care medical device: authorization, clinical trials and product development

2017  2019  2020 onward
Case study:
Colorobbia Consulting and NANOMED Project case

• **Assessment:**
  • Medium size company
  • RRI Maturity Level: Strategic
  • Tech: Nanomedicine
  • Regulatory regime: nanomaterials, medical devices, ATMP products;
  • Time to Market: 5-10 years

• **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)
Case study:
Colorobbia Consulting and NANOMED Project case

• Reflect & define (significant 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

• Experiment & Engage:
  • Key actions: Ethical analysis (>5 meetings), in-house stakeholder dialogue (20 participants), Prisma external dialogues (3 events)

• RRI Roadmap: 9 areas of actions selected
An example: Colorobbia Consulting, NanoMed project

RRI VISION
Realize a nano-based platform for personalized and point of care therapy, for a highly effective, accessible and affordable treatment of severe diseases.

Drivers and challenges
- Demand for better diagnosis and efficacy in therapies
- Need for long term research investments
- Patient-centric procedures, for both clinical trials and cure
- Increase of patients survival and improvement of their life quality
- Ethical concerns/patient’s rights
- Regulatory uncertainties
- Mismatch of personalized therapies with existing healthcare system
- Safety of nanomaterials along the product life cycle
- Risks (potential/perceived) of use of NM into the body
- Resources and competences for RRI
- Societal acceptability

Risks and barriers to address
- Ethical concerns/patient’s rights
- Regulatory uncertainties
- Mismatch of personalized therapies with existing healthcare system
- Safety of nanomaterials along the product life cycle
- Risks (potential/perceived) of use of NM into the body
- Resources and competences for RRI
- Societal acceptability

RRI approaches, tools, actions
- RA: Ethical and social impact analysis (scenario analysis)
- IN: Stakeholder dialogues
- RE: ELSA monitoring Board (precaution, beneficence, dignity, informed consent, data protection and data ownership)
- RE: Early use of qualified standards for quality, reliability, safety
- RE: Safe by design for NM
- RE: Research & modelling of the system (long term efficacy)
- IN: Dialogue on business models/costs/benefits with investors, healthcare system (local) authorities
- IN: Communication, dialogue strategy toward professional, patients and society

R&I technologies and products
- Nanotech-related integrated platform for diagnosis and treatment (theranostic) of cancer and nervous system diseases
- Portable medical devices for personalized, point of care cell therapies production

Drivers
- Challenges
- Risks & barriers
- RRI actions
- RRI actions done during the pilot
- Tech & products

Present/short term
- Medium term
- Long term

Time to market: around 10 years

Funded by the European Union
https://www.youtube.com/watch?v=IL5CwR1QOGI&feature=youtu.be
Thank you.

pimponi@airi.it
info@airi.it