PRISMA

PRISMA PILOTS RRI ROADMAPS:

Colorobbia

CEN workshop background document

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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)

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.

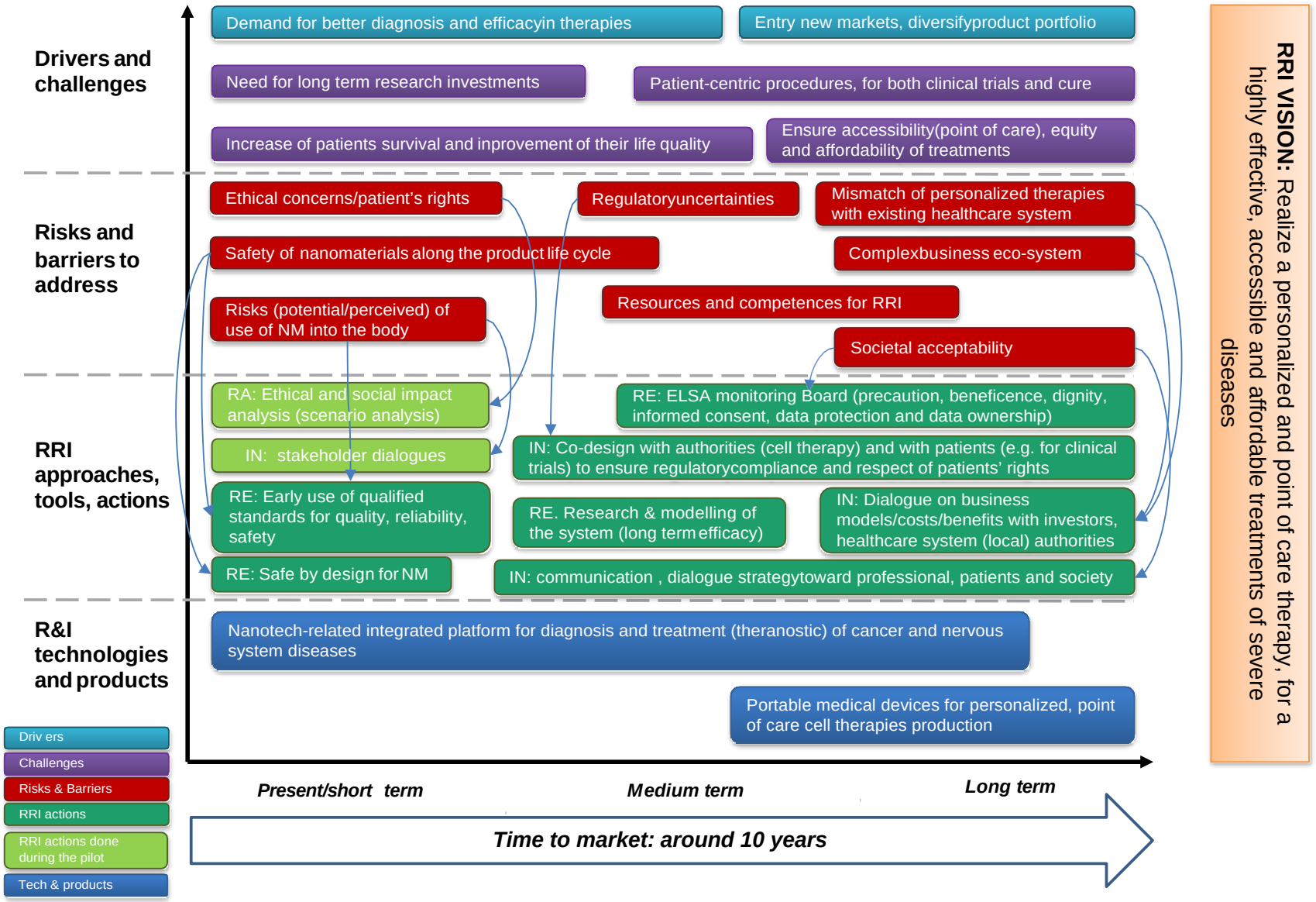

Figure 1: Colorobbia Consulting, PRISMA RRI roadmap