

A SMART Map for 3D Printing in the Biomedical Field (3DMed)

Executive Summary for Industry

The SMART Map is a **tool that helps businesses** address issues of **social** and **environmental responsibility** they face in their innovation processes. It is based on the **Responsible Research Innovation (RRI)** approach promoted by the European Commission and it provides different stakeholders with practical suggestions on how to promote these principles.

The SMART Map proposes **a route that guides industry** from the *current scenario of 3DMed* towards the *implementation of RRI practices* and their *potential benefits for companies*, through a series of *suggested actions* and concrete examples collected during a pilot.



RRI: why you need to get there

RRI practices in the 3DMed industrial context have benefits at various levels for the industry sector

- For a **Chief Technology Officer**: when you carry out a technology assessment or need to update your product roadmaps, SMART-map tools can help you gather higher-quality input and run the exercise in a more customer-focused manner. Tools like a **RRI 3DMed multi-stakeholder workshop** can contribute to understand and anticipate uncertainties, concerns and expectations around both products and processes (for example safety, affordability and timing issues) of end users, thereby building a relation of trust with society and the market, which in turn increases the company's reputation. Furthermore, the tool can help implementing new strategies to improve the quality and the safety of products and finding new business opportunities by adopting an inclusive and participatory approach. As emerged from the 3Dmed pilot, focusing on revising standards and certification approach for the 3D printed medical devices, the **RRI 3DMed multi-stakeholder workshop** could be a concrete means to identify the needs of the stakeholders and to unleash the potential of 3D printing in biomedicine, also in terms of personalisation of products. "So far Medical Device Certification focused on technical aspects mainly; thanks to the collaboration with SMART-map we are now including the ethical dimension which will increase the value our companies will provide to patients, doctors and the rest of stakeholders", highlighted Alessio Giuliani, SYMBIONICA Project Coordinator, involved in the 3Dmed pilot experience.
- For **Management and the R&D and Product Development**: SMART-map tools can help translating the company vision into requirements for R&D process, and implement "agile ways of working". **RRI training, RRI self-assessment** and **RRI score** can foster the self-assessment of companies so to identify new research, development and management priorities or to strengthen existing ones in line with societal needs.
- For **Commercialisation and assessment**: SMART-map tools can help addressing gaps in health technology assessment, and particularly in patient-reported outcomes, to know better their audience and prepare for regulatory approval. Tools like **RRI training, RRI self-assessment** and **RRI score** can sharpen communication activities and goals, presenting RRI-compliance as an added value. Moreover, **RRI 3DMed multi-stakeholder workshop** can increase the companies' awareness about their innovation ecosystem, enlarging the community of stakeholders and improving the relationship with them, and positively influencing the innovation ecosystem governance both in terms of avoiding over-regulation for new technologies and including more voices that can prevent the development of a monopolistic system composed of a small number of big companies.



RRI: how you get there

A list of suggested actions the industry sector could implement to help moving 3DMed towards RRI

1. Provide **RRI training for employees and management** in order to develop a proper **awareness of industrial role** within the **responsible innovation ecosystem**
2. Foresee and execute **multi-stakeholder processes**, in which **patients' voice is key**, with the aim to be more fitting for that specific innovation sector as well as RRI-compliant
3. Promote and participate in **multi-stakeholder dialogues**
4. Introduce **RRI-related assessment methods** to evaluate the **social and environmental impacts** of the company's core business
5. Exploit **RRI compliance as a strength** for the company **to be communicated** to a variety of stakeholders (policymakers, public and private funders, societal actors, patients and end-users)
6. Build-up a **community of industrial RRI-responsive actors**



Needs, challenges and opportunities for RRI

Key highlights in the current scenario of 3DMed

- **Quality as a social value:** fostering the awareness of new technologies; improving the eco-balance of 3D processes and products; scaling up personalization
- **Safety, privacy and sustainability regulation and rules:** providing space for experimenting; putting measures in place helping to avoid accidents; respecting patient privacy; considering environmental impacts
- **Building bridges among communities and patients' engagement:** including vulnerable groups; finding spaces physically supporting the interactions; involving patients in the planning process; collecting patients' input
- **New business models and new professionals:** preventing the formation of a monopolistic approach of the big companies; implementing new business models, partnerships and professional profiles; elaborating a new type of logistics
- **Responsible Innovation ecosystem:** giving all stakeholders the opportunity to talk about their needs and influence the solutions



Societal Mobilisation Goals

Where the multi-stakeholder activities believe the sector should go

- **The need to approach RRI as an ecosystem:** it is essential to build and maintain interactions among different players at all levels of the innovation process.
- **The need to establish framework conditions:** it is pivotal to implement standards and certification processes as well as incentives and rewards that could promote the of RRI practices.
- **The need to invest in communities:** there is a clear need for virtual and physical meeting places, to foster cross-stakeholder collaboration and build communities who practice RRI.

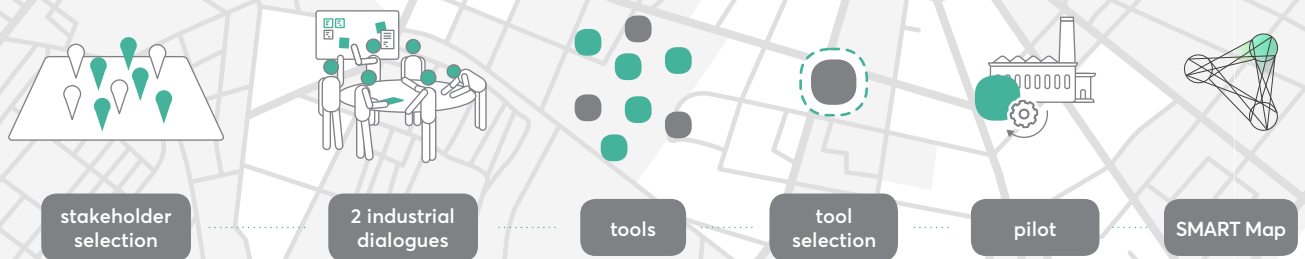
How the SMART Map has been drafted

The SMART Map is the outcome of a process that began with two workshops, the *Industrial Dialogues*, that took place in **Munich** (Germany) and **Milan** (Italy). A broad range of stakeholders participated in the workshops and produced a number of proposals of RRI 3DMed toolboxes.

Selected toolboxes have been tested by the **SYMBIONICA** consortium, an EU-funded project coordinated by Sinteia Plustek (SME based in Milan which develops medical implants using 3D printing technology).

The Munich and Milan Industrial Dialogues

- 46** participants
- 17** actors from the Industry sector
- 9** Civil Society Organisations
- 12** research institutions
- 6** complex toolboxes co-designed by participants



The pilot phase: testing two RRI toolboxes in the 3DMed industrial context



The tools:
RRI Training
Multi-Stakeholder Workshop

Pilot organization:
SYMBIONICA project



Two tools have been selected and tested within the SYMBIONICA project: an **RRI Training** for SYMBIONICA consortium and a **Multi-Stakeholder Workshop** with external stakeholders. The workshop was aimed at exploring and developing a strategy for promoting the certification of the process to produce 3Dprinted medical devices, in line with the RRI principles. The two selected tools have concretely contributed to **better addressing some key objectives** of the project, thereby also **better aligning the project's outcomes with RRI principles**.

