The experience of the Pilot

3D printing in the biomedical field (3DMed) Pilot was a relevant and successful step in the project. The main purpose of the pilot was to test, analyse and appraise if the RRI tools, co-created and co-developed with the societal actors during the Industrial Dialogues in Munich and Milan, can be effectively implemented within the innovation pipeline of 3DMed enterprises to promote the integration of an RRI approach in the industrial realm. The results demonstrate that such processes are feasible and can bring benefits and advantages to companies as well as to other stakeholders of the larger innovation ecosystem.

Sintea Plustek s.r.l., an SME based in Milan, which develops medical implants using 3D printing technology, was the chosen company to test and implement the pilot activities. The company is also coordinator of the EU funded (under Horizon2020 Framework Program) SYMBIONICA (Reconfigurable Machine for the new Additive and Subtractive Manufacturing of Next Generation Fully Personalized Bionics and Smart Prosthetics) project, which focuses on the manufacturing of personalized bionics, smart endo-and exo-prosthetics. The SYMBIONICA consortium is composed of three large enterprises, six SMEs and two RTD partners. In agreement with the SYMBIONICA steering committee, the SMART-map pilot was extended to the whole SYMBIONICA project. Two RRI tools were selected and tested in the 3DMed pilot: 1) RRI Training for SYMBIONICA consortium 2) A Multi-Stakeholder Workshop with external stakeholders, aiming to explore and develop a strategy for a certification of the process in line with the RRI principles to produce medical devices and implants, deploying 3D printing technology.

Currently, the certification of medical devices as well as those which are produced through additive manufacturing (3D printing) technologies, is focused on the product. Certification is mandatory for all the medical products before entering the market, in the EU (CE marking) as well as in the US (FDA marking). However, considering the fact that 3D printing process can affect the proprieties of materials used for manufacturing medical devices, a certification focused on the product

cannot properly guarantee the safety of these kind of medical devices. In addition, a product certification approach is costly, extends time to market, and reduces affordability and access to the products, thus impedes to set free the full and disruptive potential of 3D printing in biomedicine. In short, a conventional approach to certification focusing on the product is not suitable to ensure quality, safety and RRI compliance. Instead, a certification of the process for producing 3DMed products could guarantee high quality and safety standards for patients, delivering customized medical devices while at the same time allowing for a seamless incorporation of RRI principles across the value chain.

In view of the two selected tools, the pilot was composed of two main phases connected to the organisation and the delivery of the RRI training and the multi-stakeholder workshop. The primary goal of the training was to convey to the consortium partners the meaning of RRI in the industrial realm as well as to provide RRI knowledge to be used and adopted within the SYMBIONICA project objectives. An ad-hoc format was designed by the two partners involved in the pilot (Bassetti Foundation and Fraunhofer ISI) to accomplish these goals. The training was held on 4th December 2017 during an Annual Meeting of the SYMBIONICA project in Patras, Greece.

The major scope of the multi-stakeholder workshop was to start a dialogue with external stakeholders not involved in the project, on revising the rules for 3DMed, proposing and exploring potential new options related to process certification for 3D printed medical devices and inserting RRI elements. The workshop, called "Toward responsible rules for 3D printing in biomedicine", took place on 21-22 March 2018 in Milan, Italy with the participation of diverse groups of European stakeholders and professionals. The exchange with the participants highlighted that a novel form of certification in 3DMed is a hot topic in the community and such experiences of multi-stakeholder dialogue and exchange are much needed in this field.

The overall 3DMed pilot has fully met all the initial expectations of SYMBIONICA, and 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. In particular, SYMBIONICA consortium has:

- Assessed the SYMBIONICA objectives through the RRI lens, unveiling that some elements of responsible innovation were already at the core of the SYMBIONICA project (i.e. the engagement of relevant stakeholders through the development of the SYMBIONICA ICT collaborative design platform);
- Developed concrete ideas on how to use the acquired RRI knowledge during the pilot, presenting RRI-compliance as a strength and an added-value in the project pipeline in their dissemination actions;
- Planned a thorough evaluation of social impacts of project products by quantitative estimation of potential cost reductions, which will increase the accessibility of personalized prostheses to a wider range of patients; reduction of environmental impacts in terms of energy and resource consumption due to 3D printing fabrication compared to traditional manufacturing; benefiting the patients due to high level customization and short delivery time;
- Designed a plan for the certification of the SYMBIONICA products and processes, which will ensure a strong relation between technical achievements and social impacts.

The pilot has also delivered evidence with regard to the applicability of RRI in 3DMed: co-designing new technical but RRI-compliant ("RRI by design") standards, upon which certification can be obtained, could be an efficient way to bring RRI to industrial actors. Such an approach can most likely be extended to other sectors and innovation areas.