Introduction

Field specific ecosystem

3D printing is an interdisciplinary field that requires bringing people with different professional and disciplinary backgrounds together. The production process for implantable prostheses, for instance, involves not only the patient and the surgeon but also the radiologist, the hospital management and suppliers of 3D printing products and services. The question of liability is particularly tricky considering the production process ranging from making a CT scan and manual segmenting to printing the 3D model, post processing and finally the surgical implantation. The application of 3D printing to biosciences and biomedicine has the potential to transform diseases' prevention, diagnosis and therapies, as well as post-surgical rehabilitation. This new technology is already being used to create objects and prosthesis: many biocompatible materials are 3D-printed for orthopaedic applications (prosthetic hands, arms, jaws, legs, knees) and some devices have also been implanted in patients. The technique can encompass dental applications (crowns, bridges, stone models and a range of orthodontic appliances) and be used for the production of hearing aids and general medical devices. In the future, bioprinting could be employed for the fabrication of hearts, livers, kidneys and other types of human tissue and it is already a concrete approach to manufacture cartilages, bones and skin. Tissues might also serve as models for research, drug discovery or production, eventually substituting protracted chemical synthesis processes. Now, thanks to 3D printing, biomedical devices such as prosthesis and implants as well as consumables (injections, inhalators, mouthpieces, orthopaedic devices) can be custom-made, tailored to the physiological needs and anatomical characteristics of a single patient at minor time and cost. Innovation fosters bottom-up approaches in which citizens and patients have an unprecedented key role. 3D printing is not merely pertained to the medical device industry. It is a technology having the potential to increase the quality of life of patients in many ways. For

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instance, by making tailor-made products and accessories such as pens, spoons, forks and coffee holders, for instance, for individuals with physical disabilities available almost instantly, even in remote locations. 3D-printed objects are based on a pre-designed 3D digital models and can perfectly fit patients' anatomy, physiology, and therapeutic needs.

Advancing 3D printing brings together stakeholders at the intersection of different domains. Universities conduct extensive research in bioprinting in 3D with the aim to produce artificial tissue, organ constructs and other biomedical applications of additive manufacturing. They also represent a significant link between research institutions and clinics through university hospitals. In the private sector, CAD/CAM software developers and data storage companies play a key role. The industrial sector, which includes, for instance, 3D printer manufacturers, producers of 3D printing materials, 3D scanner producers, 3D printer designers and fablab / maker spaces, utilizes and further develops technologies with the aim to make customized prosthetics, implants, fabricated organs and tissues as well as personalized medical products, drugs and equipment part of biomedical everyday life. Intermediaries build a link between the industry and end-users, and get involved in the process of 3D printing regarding the enforcement of intellectual property rights for the end-users. Bringing 3D printed products and related services to market requires capital, which brings public funding agencies, venture capitalists and start-up incubators into the picture. Guaranteeing patient safety and product quality involves regulators, including ethics commissions, who review the technological, ethical and legal basis for patients, product liability and data protection. While they are fundamental for bringing innovations related to 3D printing in the biomedical field to the market, the demand arises from patients, medical professionals and intermediaries. The latter encompass health insurances, professional associations and trade associations that mediate between demand and supply. Patients, as the end-users, are the key beneficiaries from innovations in 3D printing. Many of them are represented by disease-specific patient groups, amputee associations and other civil society organisations.

3D printing in biomedicine has a great potential to broaden the involvement in and thereby to democratise production. However, since the technology is becoming more and more pervasive, new questions intertwined with RRI themes arise. This promising sector is already facing tremendous challenges with regard to managing safety and security issues and to the testing of efficacy levels. For example, what could be the role of citizens in improving the safety and security processes? The SMART-map project had the objective of finding some possible answers to this question and other issues of concern. By involving 3D printing machine producers, software and services developers, advanced materials producers, end-users as well as civil society representatives, it developed a 3D Printing smart map to fully exploit the potential of this promising technology.

The present document, a SMART Map for the responsible advancement of the 3D printing in the biomedical field, contributes to addressing this ambition. It is the joint product of an inclusive process of co-design, involving representatives from relevant industries, research institutions, healthcare, the public sector, civil society, and patients' organisations.

The context of responsible research and innovation

The European Commission describes Responsible Research and Innovation (RRI) as an approach which "implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society".[1]

[1] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation (accessed June 29, 2018)

Demonstrating how responsible innovation can be implemented in an industrial context remains an open task, as is providing evidence that responsible innovation is an effective approach to opening up the innovation process to social actors, ensuring the quality of products and processes. The European Commission sees a need for an improved business governance that deeply embeds creativity, scalability, responsiveness, circularity and societal engagement. To achieve this goal, it supports actions that aim to increase public-private partnership in the innovation process, to increase the social value and acceptability of innovation, and to facilitate the emergence of new business models that embed sustainability and social responsibility throughout the entire business process.

It is in this context that the SMART-map project operated.

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