A SMART Map for the 3D printing in the biomedical field

Needs, challenges and opportunities

In the context of 3D printing in the biomedical field, the identified needs, challenges and opportunities require an RRI framework to be handled in an open and inclusive way. Obstacles to the implementation of RRI cannot be identified in isolation from the specific challenges characterising a given field of innovation.

According to the experiences collected during the Industrial Dialogues, the responsible advancement of 3D printing in the biomedical field depends on the capacity to develop further the innovation ecosystem according to the following principles:

A) Quality as a social value

The awareness of new technologies (as the application of 3D printing for the biomedical field can be considered) should be enhanced and fostered by the innovation ecosystem as a means to improve the production quality. 3D printing allows implementing highly improved or entirely new medical treatments. Nevertheless, the eco-balance of 3D processes and products/applications should be improved. Developing cost-competitive 3D printed products that meet the needs of the market is important. Yet, additive manufacturing offers personalized treatment opportunities, which are sometimes not cost-competitive. Scaling up personalization is a significant cost challenge and raises issues such as accessibility, affordability and social justice. Regarding personalized products, it should be considered that there are some materials, used for 3D-printed implants or prosthetics, which should be excluded from being applied in products for certain patient groups (e.g., some materials contain pork gelatine).

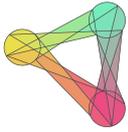B) Safety, privacy and sustainability regulation and rules

Regulations in the 3DMed field should keep pace with innovations, and certification should ideally be in place before products are marketed. Sufficient space for

experimenting should be provided, collecting different perspectives, voices and actual experiences before implementing new regulations and rules (i.e. certification of a new form of intellectual property, novel and 3DMed-specific technological standardization rules). It is beyond dispute that there should be a strong focus on patient safety. This also includes the need to revise existing rules applied to certify 3DMed products and putting mechanisms and measures in place helping to avoid accidents related to electronic components in implants. Patient data is specific and therefore patient privacy is a major concern to be respected and effectively safeguarded in 3D printing applications and related rules. A prerequisite for privacy is security. The ecological problems and environmental impacts should be also considered, as the generation of waste could be increased using 3D printing in comparison to conventional treatments. At the same time, a reduction of energy consumption could be also achieved. Therefore, further reflections on environmental impact should be taken into account in the formulation of new rules.

C) Building bridges among communities and patients' engagement

All stakeholders need to be involved in the 3DMed process. The interaction and cooperation between patients, health professionals and the industry should be enhanced. Patients' associations and vulnerable groups (such as elder people) should be part of this exchange. There is the need to find adequate spaces and fora physically supporting the interactions among communities. Under certain conditions, FabLabs can provide effective opportunities for such productive interactions. Patients should be provided with opportunities to actively participate in the planning process of the 3D printing of an implant or prosthesis and be able to influence the design of the product. Collecting patients' input could also help the industry to develop products in line with the patients' needs. Patients' perspectives should also be integrated in revising or producing new rules and procedures for the sector.
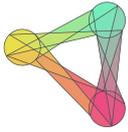
D) <u>New business models and new professionals</u>

The formation of a monopolistic approach of the big companies should be prevented, so that SMEs, start-ups, small firms, relevant actors and drivers of this innovation field have a chance to exist and prosper in the market. There is a potential for the implementation of new business models in the biomedical industry, which leads to the need for new partnerships and new professional profiles (e.g., entrepreneurial fablabbers and designers as intermediaries between different kinds of expertise and experience). New jobs may allow the establishment of new kinds of professionals, who are aware of the communication needs between industry, research, and civil society and can play an active role in strengthening collaboration among communities. There is also a need for a new type of logistics, which involves 3D printing and RRI, and clarifies the connection of the different parts of the 3D printing value chain.

E) <u>Responsible Innovation ecosystem</u>

RRI gives all stakeholders the opportunity to talk about their needs and thereby influence the solutions that mark the end of the value chain. RRI has to be realised in a way that all parties feel involved in the facilitation of the ecosystem. All stakeholders who are sharing the benefits and the risks of innovation within the ecosystem have their own role that should be acknowledged.

Societal Mobilisation and Advancement of Responsible Industrial Technologies

One of the objectives of SMART-map was to design a flexible RRI approach to be implemented in industrial innovation processes. Insights from the inclusion of a wide range of societal actors and the co-design approach used to develop this SMART Map suggest a number of framework conditions that need to be in place in order to support the advancement of responsible industrial technologies.
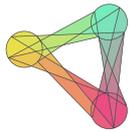
1) The need to approach RRI as an ecosystem

While this project focused on industry, any RRI approach requires the involvement of a large number of different players. The interaction of these players, and the instruments which enable it at all levels of the innovation process, becomes a central element for the implementation of RRI. The adoption of principles of RRI governance, such as those described by the Res-AGorA Responsibility Navigator[1], should be considered as fundamental. Co-design, inclusion and participation are essential to mobilise the necessary resources and players for RRI to become a reality and penetrate industry at large, starting from institutions and local communities.

## 2) The need to establish framework conditions

The need for standards and certifications has been highlighted multiple times during the Industrial Dialogues of the project. Standards and certification processes induce organisational and cultural transformation, firstly because the legitimacy they grant incentivises compliance, and secondly because they trigger review and assessment procedures, which can and should involve multiple stakeholders. Several proposals for certifiable standards already exist, but lessons from the pilot highlight that a further convincing and feasible approach is to embed RRI into technical standards. The main idea is to establish standardization processes that are RRI-compliant by design. Such an RRI-inspired approach would entail no additional burden or costs since it is not a further and separate certification for RRI, and an easy way to simplify and speed up the embracement of RRI by the industrial actors.

Additionally, there is a clear need to provide incentives and rewards for the adoption of RRI practices: conditions to access public funding, awards and evaluations, and specific funding for transformative processes. An important aspect to create

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[1] http://responsibility-navigator.eu (accessed June 29, 2018)
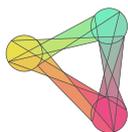
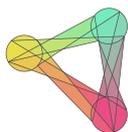capacities is also to include RRI practices as an element of the evaluation for career progressions.

3) <u>The need to invest in communities</u>

The proposals emerged during the workshops suggest the need for sufficient virtual and physical meeting places, to foster cross-stakeholder collaboration and build communities that practice RRI. Local institutions play a pivotal role to invest in such fora.

Actions for the Implementation of Responsible Innovation in 3DMed

How to concretely tackle the needs, challenges and opportunities in implementing RRI within the industrial field of 3D printing in biomedicine? Below, a set of proposed actions is listed, separated into different categories of "RRI enablers", communities of actors who have a role and a stake in such process. These suggested actions emerged as consequences of the two multi-stakeholder dialogue events held in Milan and in Munich, of the 3DMed pilot experience as well as of further multi-stakeholder events on cross-cutting issues for Responsible Innovation in the context of the project. Thus, the aim of this SMART Map is to encourage the RRI enablers to take into account this set of actions in order to pursue the goals of societal mobilisation in the field of 3D printing in biomedicine. All the suggested activities are not to be understood as an exhaustive list of elements to be taken into consideration, but as a starting point of accomplishments to get RRI actionable and concrete in the industrial realm of 3D printing in the biomedical sector.

| Action	Description	Who
3DMED 1	Develop and provide RRI training for employees and management in order to highlight what kind of advantages RRI can bring to companies in terms of better products/services, accountability, social impact, virtuous exchange with the local context and to develop a proper awareness of industrial role within the responsible innovation ecosystem. This can be a starting point to devise a long-term RRI strategy.	Industry
3DMED 2	Foresee and execute multi-stakeholder processes, in which patients' voice is key, to explore crucial issues that could help the company to release responsible products and services, but also to question and even propose to revise rules and procedures in place (i.e. standards) with the aim to be more fitting for that specific innovation sector as well as RRI-compliant.	Industry
3DMED 3	Promote and participate in multi-stakeholder dialogues to discuss hot topics of the sector and to propose concrete solutions that can foster the advancement of the field.	Industry
3DMED 4	Introduce RRI-related assessment methods to evaluate the social and environmental impacts of the company's core business.	Industry
3DMED 5	Exploit your established 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.	Industry
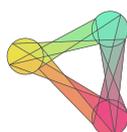
Action	Description	Who
3DMED 6	Build-up a community of industrial RRI-responsive actors. The more the community grows, the more it will be an advantage to take part, in terms of visibility and critical mass.	Industry

Action	Description	Who
3DMED 7	Get involved in innovation initiatives and processes along with industrial actors with genuine willingness and avoiding skepticism with the aim to contribute to a more responsible innovation process.	CSOs
3DMED 8	Advocate for a fair and transparent engagement of patients (and patients' representatives) within industrial innovation pathways	CSOs

Action	Description	Who
3DMED 9	Promote and introduce the RRI approach as a parameter in the evaluation of proposals and the awarding of grants and funds for industrial actors	Funders
3DMED 10	Conceive and support innovation projects which take into account a multi-stakeholder involvement	Funders

Action	Description	Who
3DMED 11	Explore new measures to enhance and reward industrial actors adopting an RRI approach	Policy makers
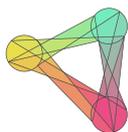
3DMED 12	Favour the adoption of rules for innovative sectors, which are RRI-compliant by design	Policy makers
3DMED 13	Introduce multi-stakeholder governance practices at all levels of policy making, particularly with the aim of improving the users experience as a relevant perspective to be taken into account	Policy makers

Action	Description	Who
3DMED 14	Favour RRI embedding in the industrial realms by focusing on concrete and real needs of the actors, assisting them in finding and implementing the most feasible tools to embrace effectively RRI, understanding constraints and peculiarities of the business sector.	RRI community
3DMED 15	Build-up alliances with other "responsible" innovation approaches and practices (e.g. CSR, social innovation, B-corps, etc.) since this exchange can generate new ideas on how to foster the adoption of RRI principles within the innovation pipelines.	RRI community
3DMED 16	Advocate for an effective take up of Responsible Innovation by also tackling critical issues (i.e. involving societal actors and reward their contribution; dealing with open access requirements and IPR and trade secrets) and exploring potential solutions in pursuing such processes.	RRI community