Report on the Responsible Industrial Development of 3D Printing in the Biomedical Field (3DMed)
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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
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”.

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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.

**How the SMART Map has been drafted**

*Stakeholder mapping and the Industrial Dialogues*

The SMART Map for 3D printing in the biomedical field is the outcome of two workshops that brought together actors from industry, civil society and the public sector with the goal to co-design tools that will enable businesses to address questions of social and environmental responsibility they face in their innovation processes. The workshops took place in the first half of 2017, in Munich, Germany (February), and in Milan, Italy (May).

The project designed a custom format for these workshops, called “Industrial Dialogues” that builds on the two principles of inclusion and co-design. Inclusion is key to advancing responsible innovation because different stakeholders represent diverse viewpoints, experiences and concerns. The workshops recruited a broad range of stakeholders, provided enabling conditions for stakeholders to deliberate among equals regardless of their background, and encouraged mutual learning. Co-design leveraged inclusion and was supported by an interactive workshop format that led in several steps from participant-defined concerns to concrete tools for responsible innovation.
In preparation of these Industrial Dialogues, the SMART-map team mapped the organisations, which already actively partake in the innovation systems of 3D printing in the biomedical field in Germany and Italy with a focus on the greater Munich and Milan area. In addition, the team tried to include organisations that are not directly involved in the innovation system today, but whose voices ought to be heard in order to ensure the inclusive and responsible development of this health technology area.

In a self-classification exercise at the beginning of each workshop, many participants described themselves as representing more than a single institutional position. Moreover, the participants complimented the diversity of viewpoints included.

**Introduction of the workshop & identification of key topics**

In the initial session of the workshop, the participants were provided with background information about the project’s aim, the policy context of responsible innovation, and the state of the art in 3D printing in the biomedical sector in order to create a common foundation. Next, the participants were divided into groups for a first breakout session, with the goal to brainstorm about needs, challenges and opportunities they perceived for advancing 3D printing in biomedicine innovation in a responsible manner. The groups brought their findings back into the plenary where they jointly identified similarities and convergences between their findings, leading to a number of discrete themes. These themes then served as the basis for the next set of group work.

**Fast prototyping**

The participants were asked to develop ideas about how innovation in 3D printing in biomedicine could be better aligned with the topics outlined in the commonly identified themes. Within the same breakout session, the groups proceeded to ‘fast prototype’ tool proposals that translated these ideas into concrete actions that could empower companies to innovate responsibly. As the term fast prototyping suggests, the priority was to create many tool proposals in a short amount of time. Each breakout group presented their tool proposals during a subsequent plenary session, where the participants could vote for those proposals they considered particularly
relevant and for those they would like to develop in more depth during the final breakout session.

**Design and mock-up of tools**

During the final design session, the activity had a deliberate ‘hands on’ character. As the participants went about creating more detailed prototypes of their preferred tool proposals, they were encouraged to build a **physical** model with tools and craft stuff such as scissors, glue, play dough and string. The design teams received comments from the other groups and had a chance for a final round of improvements, before presenting their designs in a concluding plenary.

**Toolboxes for the Advancement of Responsible Industrial Technologies in 3D Printing in Biomedicine**

The Industrial Dialogue workshops produced a number of proposals, which, to varying extent, put RRI principles into practice. It has to be noted that the participants broadly shared and strongly emphasised that responsible innovation depends on an ecosystem of diverse and interacting players. This insight has the consequence that tools for responsible innovation in industry should not be confined to a discrete action taken within a specific company. Rather, it is in multi-stakeholder constellations that a company can cooperate for instance with a hospital and a regulator to address a genuine societal concern. Because of this multi-stakeholder nature of RRI, participants proposed complex toolboxes, rather than individual tools.

The following briefly describes the proposals developed in Munich and Milan.

**The service platform in 3DMed toolbox**

**The toolbox in brief**

This tool has been co-designed by a group of participants in the Milan event and aims at developing a web market place where patients share 3D printing product
requests that can be screened and selected by physicians, who act as checkpoint actors, and produced by companies. At the same time the platform addresses the issue of RRI compliance and only companies that successfully conduct an RRI self-assessment can gain access to this platform. This toolbox aims at connecting patients’ needs to industrial production, fostering the development of personalized devices, according to a physician-mediated process. Successful patients’ case stories are also collected on the platform as valuable and inspiring information for further developments of such a multi-stakeholder exchange and collaboration.

**How does it work?**

The tool proposes a service infrastructure that is accessible to patients/patients’ organizations, industry/industries’ organizations, research centers, universities and physicians. At the first stage, stakeholders have to fill out a self-registration form (profiling) and to publish either their demand (patients need) or offer (companies product or service). In order to have access to the platform, companies are required to provide a certification that includes an RRI self-check assessment. This means that companies not RRI-compliant cannot access the infrastructure. Further access can be permitted if, after a negative response from the RRI self-assessment, the company starts procedures and initiatives to embark on RRI principles and practice.

Patients or patients’ associations classify their needs in: part of body related needs, environmental needs and new solutions. Companies intercept these needs proposing new products and services, which are submitted to a technical review and to a scientific/medical evaluation. Research players as well as other stakeholders (i.e. Fablabs) also participate to the assessment process. If the product is approved, it is delivered to the patients and then described in the platform as a case story in order to inspire further experiences. If the product is not approved by the evaluation group, it can be modified, improved and then re-submitted for a second round of evaluation.

All the products developed thanks to the platform are continuously assessed in an ongoing process. A post sale service is provided by the companies.
Key requirements and open issues

The service-platform in 3DMed cannot work if there is not a broad participation of patients, companies and physicians. Such a service infrastructure requires an initial investment to set-up the platform, to recruit and engage participants. It is not clear who should be the owner and the manager (public institutions?) and what degree of independence between the owner and the participants can be guaranteed.

Once the patient’s needs are released on the platform, the selection process of the companies that should answer to these needs is not clear. It was proposed that the patients’ association can mediate the process and the “matching” method of needs and products/services. During the discussion on this issue, participants observed that if the competition is based on the means of production, big industries will always prevail over the small companies. In order to facilitate an active role by small and medium enterprises, the focus should shift from the machines to the production process.

Participants also discussed about the benefits of this tool. From the companies’ perspectives, the tool can be promising as it can increase their portfolio; it can help them in developing better customized products and it can improve their business. The service platform and the interaction between patients and researchers can lead to the development of new markets. Successful case stories could also inspire ideas to set-up new companies that could easily have access to an already existing broad community.

Some open questions relate to intellectual property issues: the more the products and the processes are open, the better it is, according to the participants, even if they also highlighted that intellectual property rights should be somehow acknowledged.

RRI 3DMed open course toolbox
The toolbox in brief

This tool has been developed during the Milan ID event. It consists of an open training for citizens and professionals on RRI in 3D printing. It is structured as a multi-module, open and blended course to train citizens/activists/patients as well as professionals in 3D printing and related RRI issues. The course is intended to be delivered on-line and off-line both at companies’ premises and at makerspaces. The name of the toolbox, according to participants’ agreement who have developed the idea, is “3ducare”, summarizing the aspects of 3D printing education as well as the idea of care. The toolbox was divided in two pathways: (1) a professional course that aims at equipping professionals with 3D printing RRI-related skills and competencies, and (2) the development of an awareness programme addressed to citizens on promises and potentials of 3D printing in biomedicine, exploring also the societal impacts.

How does it work?

Professional course: radiologists and imaging professionals, surgeons, and technicians (in particular those who can be impacted by 3D fabrication and manufacturing) need to be trained in technical specificities and competencies of additive manufacturing for biomedical products such as implants or prostheses. These kind of skills are at the cross-roads of several sectors, and consequently comprehensive training is not yet provided by companies or institutions. Moreover, as the application of 3D printing in biomedicine entails several issues in terms of liability and regulatory procedures that are quite new or forthcoming, or open questions on patients’ data preservation and ethical concerns, a specific training in these aspects should also be provided to equip professionals in the field with a full and effective range of competencies.

Citizens course: Different actions can be addressed to and organized together with schools and patients’ organizations to promote discussions and tinkering activities on 3D printing technologies thanks to hands-on activities carried out in Fablabs, where people can try out how to use 3D printers to produce medical devices and increase their knowledge on the topic. Storytelling activities can be also carried out in neutral
spaces such as libraries or museums. Patients and citizens can take advantage of knowing more about such a technology. As increased awareness of the impact and the benefits of 3D printing in medicine, patients might choose hospitals and care institutions that offer this kind of approach. Awareness campaigns and open courses can be a benefit also for companies because knowledge and interest can create a new demand, thus a new market. Touching points between the two pathways – professional and public training – have been also foreseen.

**Key requirements and open issues**

The professional part of the tool should be funded by public institutions (at central or local level) as well as by the industrial sector because thanks to such training, companies could improve their chances to hire highly skilled professionals. Since these activities are grounded within local settings, the contribution of local public institutions – i.e. municipalities – is crucial.

Companies, which act as promoters and drivers of the tool, may offer training in hospitals and universities. A similar approach, called Fab Academy\(^2\), by which this toolbox has been inspired, is pursued by the wide community of FabLabs coordinated by the Fab Foundation. The missing part of Fab Academy is the RRI skills and experiences to be embedded in the course.

**RRI register of 3DMed cases toolbox**

**The toolbox in brief**

This toolbox has been co-designed by a group of participants in the Milan event. This toolbox is intended as a repository of activities, projects, processes, and actors dealing with RRI (and certified in acting accordingly) in 3D printing in biomedicine. Its main objective is to support the design and development of products in this realm

that are affordable and certified. The register is based on RRI principles and on affordability/efficiency basis. It is composed of several concentric layers. The register works in the context of a niche market where innovation and public funds dominate, in contrast to the mass market that is dominated by private capital. The advantages of being part of the register come with the positive reputation of belonging to this niche group (i.e. access public funds, trust seed in crowd-funding campaigns). The register is a method to screen technical, economic and social quality of products and processes in 3DMed.

**How does it work?**

Different players can access the register (i.e. companies, public, clinicians, etc.). A company might have a particularly innovative printing material, another one a specific printer, and a clinical team can be puzzling over a particular problem. Each of these assets compose a layer in an onion-like structure. To access the register, actors earn an RRI score, based on the pillars of RRI – gender, public engagement, science education, open science, ethics. Low RRI score stakeholders can improve their ranking and move towards the center of the register.

The registration helps players to share their information, activities and products. It is public and built on a community of trust. The system helps the participants to locate each other and find synergies between their needs and products.

The registration of 3DMed cases answers the questions such as: What materials are usable? Which printers can work with what kind of materials? Which printer/material can be used for a specific application? Which application is ethical?

**Key requirements and open issues**

The register needs to be managed by public European authorities or other public actors. The RRI barriers to the entrance can be assessed by applying a sort of key performance indicators (KPI). Even if not fully explained, the register is not only for companies since patients can be represented in the review board that advise on the correctness of the register maintenance.

Some key points need to be further discussed:
• Who is granted access to the system? One opinion propounds that actors cannot enter without a minimum level of responsibility. Another asserts that it is not a certification instrument, but an instrument of information sharing;
• The idea of the registration is to start ‘seeding’ RRI with a niche market that will be mature as the market becomes a mass market. Participants discussed if 3DMed would become a mass market.
• The registration can be modeled on existing approaches to rare diseases. Small numbers of cases potentially change the notion of evidence-based medicine.

3DMed Certification

The toolbox in brief
This certification toolbox, addressed to the 3DMed field, is one of the outcomes of the Munich event. The participants highlighted the importance of developing a tool for certification of quality to assess the production process of 3DMed products according to specific standards. In fact, 3DMed fabrication and implementation of the final product, developed by a 3D printing technique, cover several stages in which companies and hospitals interact with each other to finalise and deliver to the patients the 3D printed object as a medical aid device. The whole process can be awarded a seal of quality only if it meets the standards. Thus, a “perfect” 3DMed object can be classified as such if it is in line with these specificities. The toolbox can find a concrete application in hospitals and clinical settings and relies on some form of patients’ engagement.

How does it work?
The idea of this toolbox revolves around the fact that hospitals act as intermediaries between manufacturers and patients. The toolbox aims at evaluating the whole process of production and implementation (implant or usage) of a 3DMed object. The ethical committee of the hospital is involved in validating the process. Patients, who receive or use the 3DMed device, are involved in the certification process. The certification is valid at the European level.
Key requirements and open issues

To turn this tool into a practical instrument, a certification body is required. Participants clearly identified this toolbox as ISO standard–like even if managed and supervised by a neutral body. There are other check–list tools for industry devoted to medical products and devices, so the risk is that this kind of toolbox could be envisaged by the industrial sector as nothing new or without additional benefits. Moreover, from an RRI point of view, there is no clear understanding how RRI principles are embedded and pursued in such a process and it seems that responsibility is interpreted only as liability and safety.

3DMed Legal Check

The toolbox in brief

The toolbox has been developed by a group of participants during the Munich Industrial Dialogue event. The production chain of additive manufacturing in biomedicine entails different risks at any step of the process. The risks and the related needs to overcome the issues can be summarized as following: 1) securing the rights to use patients’ data, such as in a CT scan; 2) manual works of segmenting; 3) 3D model manufacturing; 4) post-processing; 5) therapy (i.e. implantation, delivery, usage). How to assess liability in each of these stages and how many actors can be involved in (and affected by) such a process? This toolbox provides legal guidance along the whole product cycle.

How does it work?

An initial multi–stakeholder conference, in which quality management professionals, health insurance representatives, surgeons, radiologists, pharmacists come together, is needed to negotiate and establish common Standard Operating Procedures (SOPs) for 3DMed. These procedures are not legally binding but act as guidelines for the field. A training for the actors in the sector has to be designed according to the agreed SOPs.
Key requirements and open issues

The missing part is the voice of patients in such a toolbox. According to the group, patients play a role in starting the process of accepting to use a 3DMed device for their medical treatment, but they cannot actually be defined as active players. Responsibility is understood as reaching beyond legal liability. Hence, the need for such a toolbox emerged as a key request for this interdisciplinary field in which clear regulations and rules are still missing. Nevertheless, it seems rather unrealistic that this kind of tool can be promoted by a single company instead of an industrial association or an independent body, as the group itself had highlighted.
RRI 3DMed information platform

The toolbox in brief
This toolbox has been the result of the co-design exercise performed by a group of participants in the Munich event. In essence, it is a web platform with several features. There is a space to find information on RRI principles and how they can be incorporated in 3DMed, and a room for training materials at different levels. Moreover, a 3DMed materials-repository and a social media space in which the 3DMed community can interact are part of the toolbox as well. The objective of the tool is to favour and spread knowledge and awareness on 3DMed and RRI as well as putting into contact different actors that are interested in such a topic.

How does it work?
Different players can access the platform (i.e. companies, public, clinicians, etc). Companies can have access only if they are RRI compliant. The “whitelist” of RRI virtuous 3DMed firms are listed in the platform so that patients can check who is in or out. An RRI advisory board is foreseen and composed of experts in RRI as well as representatives from all the categories of stakeholders in the field. The board has the duty of supervising the correctness of the platform usage (i.e. it is not allowed to advertise products; it is not permitted to access the platform if not RRI compliant, etc.).

Material and information within the platform are shared under creative commons licensing. Scientific publications in the field are also available according to open access rules.

It has been underlined that a gender balance in the participants of the platform has to be pursued.

Key requirements and open issues
The platform has to be managed by public European bodies or other public actors. Companies accessing the platform can gain visibility and accountability. The
limitation of the platform is that RRI-credibility of the participating companies is not based on their presence on the platform as such, but on the successful RRI certification as a prerequisite to join the platform. The toolbox functions as a collector of RRI 3DMed information rather than a trigger for innovating responsibly.
Tools proposed for piloting in companies

Selection criteria

During the second year of SMART-map, the project piloted some of the proposals that emerged during the Industrial Dialogues in three companies, one per field (Precision Medicine, Synthetic Biology, 3D Printing in Biomedicine). The toolboxes co-designed by the participants and described above are often characterised by a higher level of complexity than the one that can be achieved during the relatively short timeframe of the pilots. Therefore, the project team analysed both the six toolboxes and the ideas that were put forward during the fast prototyping sessions in order to compile a list of pilotable proposals. The aim was to identify a list of tools that could feasibly be piloted within a company. Tools in this list had to pass three criteria in order to be included to the selection process. These criteria are:

1. Does the tool address a technical question (e.g. the development of a standard for data interoperability)? If yes, exclude.
2. Does the tool contain activities performed within a company? If yes, include.
3. Can the tool be piloted within the budget and timeframe of the project? If yes, include.

Portfolio of tools

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<tr>
<td>RRI certification</td>
<td>This tool is a means for companies to enter into a “white list” of responsible enterprises and to increase their legitimacy and trustworthiness. If it can influence the access to funds and awards, it could induce organizational and cultural</td>
<td>There are existing examples of RRI or at least of responsible innovation certification, i.e. the UGO</td>
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<tr>
<td>Description</td>
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<td>RRI self-assessment: a</td>
<td>A series of evaluation steps during a</td>
<td>RRI Tools project self-reflection tool⁵. KARIM</td>
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<tr>
<td>check-list to assess RRI</td>
<td>research and innovation process can help the companies to keep on track</td>
<td>project’s “Introduction to Responsible Innovation Criteria” is a practical guide for implementing RRI addressed to entrepreneurs and innovation-support organisations⁶.</td>
</tr>
<tr>
<td>RRI compliance for</td>
<td>with their wider societal goals. Its potential to foster change depends</td>
<td></td>
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<tr>
<td>companies</td>
<td>on the commitment of the company to RRI - the tool per se is not a trigger</td>
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Transformation towards RRI compliance. However, a badly implemented standard might lead to a tick-box exercise, without spurring organisational change. While the function of a certification organ is hard to pilot, a standard’s criteria can be implemented in a company for testing purposes.

Further standards linked to ethical and societal implications of technology are currently under discussion in some specific fields as AI and autonomous systems (i.e. IEEE Ethical Aligned Design Global Initiative⁴).

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<td>RRI score: a value oriented</td>
<td>The aim is to highlight the value of transformation towards RRI ambitions by providing a concrete ranking system for companies, based on RRI-Key Performance Indicators (KPI).</td>
<td>The MoRRI Project has collected a core set of 36 RRI indicators. TRANSITION project has developed a Social Innovation Journey tool, which comprises a Responsible Innovation Grid. Moreover, some Corporate Social Responsibility standards overlap RRI features.</td>
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<tr>
<td>RRI training: a course on RRI principles and practices for the industrial sector for professionals as intermediaries between patients,</td>
<td>Such training is easy to be implemented but its transformative potential depends on whether RRI is embraced by leadership and reflected in staff performance assessments. Some difficulties in implementation could occur in small companies where the number of employees is low.</td>
<td>CSR departments in big companies. The RRI Tools project has developed some resources for RRI training, even if not focused on industry.</td>
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7 [http://morri-project.eu/reports/2017-04-12-d3.2](http://morri-project.eu/reports/2017-04-12-d3.2) (accessed June 29, 2018)
10 [https://www.rii-tools.eu/training/about](https://www.rii-tools.eu/training/about) (accessed June 29, 2018)
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<th>Description</th>
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<td>industries and other stakeholders</td>
<td>A tool to build-up local as well as international community around the topic in order to favour exchange of information and best practices, also in terms of rules and regulation needed and bottom-up driven. It does not have a transformative potential within the company.</td>
<td>There are several examples of methodologies and experiences to organize and run multi-stakeholder dialogue events, even if not focusing on 3DMed. For instance, the Co-Construction method developed in the realm of Res-Agora project[^11]. Several examples of engagement methods, even if more addressed to the general public, are listed in the Action Catalogue delivered by Engage2020 project[^12].</td>
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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.

**Benefits of implementing RRI**

Responsible Research and Innovation is a hot topic at the academic and European policy making level. Nonetheless, evidence of benefits of RRI within the industrial realm are still scattered, but rapidly growing. The modest aim of this paragraph is to
contribute to the picture as the Industrial Dialogue and the pilot experience of SMART-map revealed that the RRI approach clearly triggers a series of benefits in the industrial realm of 3DMed.

**Benefits for companies**

The main advantages for 3DMed companies in adopting RRI can be described as follows:

- Contributing to the self-assessment of companies and identifying new research, development and management priorities or strengthening existing ones in line with social needs;
- Reflecting on and implementing new strategies to improve the quality and the safety of products and finding new business opportunities by adopting an inclusive and participatory approach. Upstream stakeholder engagement is crucial both to identify the needs of the stakeholders and to unleash the potential of 3D printing in biomedicine, also in terms of personalisation of products;
- Understanding and anticipating 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;
- Increasing the companies’ awareness about their innovation ecosystem, enlarging the community of stakeholders and improving the relationship with them;
- Building a larger network and critical mass for the needs of the sector, and influencing 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 (see the pilot experience as an example for the development of a new form of certification based on the process instead of the product in the case of 3DMed that can reduce production costs while increasing the accessibility of
medtech products to a wider public and favouring a further development of the sector);
- Sharpening communication and dissemination activities, presenting RRI-compliance as an added value;
- Improving the diffusion of mass customisation and expanding market opportunities in the field;
- Providing more chances for accession to funding, intercepting the novel sensitivity of funders to social and responsible innovation.

**Benefits for other stakeholders**

**CSOs**
- Having your say and being heard in policies design of rules for innovative industrial actors, providing your point of view, perspective and expectations;
- Contributing to more fair and responsible innovation processes and to the release of safer, cheaper and societally aligned industrial products and services;
- Being rewarded for your ideas, time and energy in co-design innovation exercises;
- Being in contact with a broad range of stakeholders and potential collaborators and allies;
- Bringing patients at the centre stage of healthcare, instead of a technocratic approach.

**Policymakers**
- Designing policies, which properly address industrial and societal needs and expectations that can get citizens closer to institutions with a renewed relationship based on transparency and trust;
• Igniting a virtuous system, which promotes the advancement of responsible industrial innovation and effective and socially personalized healthcare;
• Mapping formal and informal actors to participate in existing and emerging innovation ecosystems;
• Identifying barriers and needs (e.g. normative, infrastructural, etc.) that prevent a full development and exploitation of enabling technologies in healthcare.

Funders
• Identifying and interacting with reliable innovation players that are in close contact with their local innovation ecosystem and stakeholders, and by this way improving the ability to devise long-term strategies.

Key messages

The Industrial Dialogue workshops and the pilot experience triggered an important learning process about the way RRI is perceived by different stakeholders, including the role that industry plays.

The Dialogues delivered the following key messages:

1. RRI should not be discussed as an abstract concept: the application of RRI should be embedded in addressing the key challenges in the field rather than solutions to enable industry to address those challenges in an “RRI way”.
2. Current innovation models and experiences already include RRI principles and practices even if they are not labelled as RRI. Providing a broader knowledge of RRI to industrial actors and other key stakeholders in the innovation ecosystem (through training exercises) can help to identify RRI features already in place and exploit RRI-compliance (through communication means and actions) as a strength for companies.
3. Co-design and co-construction processes, which incorporate the participation of different stakeholders, are relevant practices for the RRI implementation and can
be seen as an effective approach to discuss and revise rules and needs for the whole innovation sector.

4. The participation of the societal actors (such as civil society, patient representatives, etc.) in the 3DMed process could increase the public awareness and strengthen public acceptance of 3DMed technology in society. What is more, involvement of societal actors can contribute to deliver better products/services that are more in line with market expectations and needs.

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) New business models and new professionals**

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) Responsible Innovation ecosystem**

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\(^\text{13}\), 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

\(^{13}\) http://responsibility-navigator.eu (accessed June 29, 2018)
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 embrace 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 capacities is also to include RRI practices as an element of the evaluation for career progressions.

3) The need to invest in communities

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.

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
<th>Who</th>
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<tbody>
<tr>
<td>3DMED 1</td>
<td>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.</td>
<td>Industry</td>
</tr>
<tr>
<td>3DMED 2</td>
<td>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.</td>
<td>Industry</td>
</tr>
<tr>
<td>3DMED 3</td>
<td>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.</td>
<td>Industry</td>
</tr>
<tr>
<td>3DMED 4</td>
<td>Introduce RRI-related assessment methods to evaluate the social and environmental impacts of the company’s core business.</td>
<td>Industry</td>
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<td>Action</td>
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<tr>
<td>3DMED 5</td>
<td>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.</td>
<td>Industry</td>
</tr>
<tr>
<td>3DMED 6</td>
<td>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.</td>
<td>Industry</td>
</tr>
<tr>
<td>3DMED 7</td>
<td>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.</td>
<td>CSOs</td>
</tr>
<tr>
<td>3DMED 8</td>
<td>Advocate for a fair and transparent engagement of patients (and patients’ representatives) within industrial innovation pathways</td>
<td>CSOs</td>
</tr>
<tr>
<td>3DMED 9</td>
<td>Promote and introduce the RRI approach as a parameter in the evaluation of proposals and the awarding of grants and funds for industrial actors</td>
<td>Funders</td>
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<tr>
<td>3DMED 10</td>
<td>Conceive and support innovation projects which take into account a multi-stakeholder involvement</td>
<td>Funders</td>
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<tr>
<td>Action</td>
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<tr>
<td>3DMED 11</td>
<td>Explore new measures to enhance and reward industrial actors adopting an RRI approach</td>
<td>Policy makers</td>
</tr>
<tr>
<td>3DMED 12</td>
<td>Favour the adoption of rules for innovative sectors, which are RRI-compliant by design</td>
<td>Policy makers</td>
</tr>
<tr>
<td>3DMED 13</td>
<td>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</td>
<td>Policy makers</td>
</tr>
<tr>
<td>3DMED 14</td>
<td>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.</td>
<td>RRI community</td>
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<tr>
<td>3DMED 15</td>
<td>Build-up alliances with other &quot;responsible&quot; 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.</td>
<td>RRI community</td>
</tr>
<tr>
<td>3DMED 16</td>
<td>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.</td>
<td>RRI community</td>
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Final considerations and future directions

Field specific elements and commonalities

Besides the respective peculiarities of precision medicine, 3D printing in biomedicine and synthetic biology, the project has highlighted several commonalities among the three innovation fields. These common features include:

• the need to link the debate on RRI to concrete needs, challenges and opportunities;
• the fact that any RRI approach needs the action not only of industrial actors but also of other stakeholders groups;
• the presence of already existing de-facto RRI experiences – mainly consisting in co-designed practices involving mixed stakeholders groups – that are not necessarily labelled as such;
• the lack of specific standards and linked and proper certification measures in cutting-edge, game-changing innovation fields (even if in 3DMed there was a peculiar and relevant interpretation of embedding RRI in standards design, emerged during the pilot phase) and the difficulty for hard law to rapidly respond to fast technological advancements;
• privacy and data ethics as key issues to be taken into consideration.

Another common challenge for all three sectors (and for responsible innovation in general) is to bring RRI to industrial players as a further approach on responsibility and ethical commitment, linking up with well-known and diffused tools in industry (i.e. social innovation, CSR, B-Corp, LCA, etc.) that have overlapping elements with RRI (e.g. anticipation, stakeholder and citizen engagement, social inclusion, environmental sustainability, co-design exercises, challenge or needs orientation). Furthermore, the significant role that citizens and patients are increasingly gaining in for-profit innovation pathways, especially in the three fields explored by the SMART-map project, participating through sharing experiences, providing personal and health data and generating ideas, forces innovation ecosystems to elaborate and implement fair and transparent mechanisms and measures to reward and
compensate societal actors’ effort. A whole multi-stakeholder workshop has been devoted to this issue within the project since it is and will increasingly become a crucial element for responsible innovation.

As far as it emerged from the experience in the project, 3DMed is characterised by a strong focus on quality of the products, which is deeply connected to the concepts of safety, affordability and access for patients. Furthermore, the innovation ecosystem in this field is populated and shaped by new professional profiles, such as designers and hybrid actors dynamically interchanging between entrepreneurial sectors, healthcare provision and the societal sphere (e.g., FabLabbers and Makerspacers) who act as bridges between different communities, propel the advancement of the field forward and thanks to their infrastructures (FabLabs, MakerSpaces, digital social innovation and collective intelligence online communities) represent virtual and physical spaces for de facto RRI and co-design initiatives and experiences.

**Limitations, Challenges and Future Directions**

The project has succeeded in demonstrating that implementing RRI in 3D printing in biomedicine is not only feasible but can also provide a set of benefits for all actors pursuing Responsible Innovation and fruitfully collaborating within the 3DMed innovation ecosystem. Nevertheless, the project revealed inherent constraints ranging from reduced time both to test the effectiveness of the tools in a longer term and to properly appraise a transformative change in firms embracing RRI, to the limited chance to pilot all the tools co-designed in the first phases of SMART-map. Despite these limitations, the exploration of 3DMed through the RRI lens has provided several elements supporting the RRI community as well as industrial, societal and policy actors to address the “right” questions and to search for options that can permit the full implementation of RRI in this innovation sector. At first glance, 3DMed could be envisioned as a de-facto RRI innovation field. However, a deeper analysis and a continuous exchange with the relevant actors during the course of the project, unveiled crucial challenges for delivering sound and robust RRI practices in 3DMed,
such as technical but RRI-compliant by design standard/certification setting, as emerged in the pilot stage of the project.

We hope that this process will be a first step to favour a proper embedding of responsible innovation in 3DMed and more initiatives will follow, thanks also to our small, but in our view, valuable experience.