A SMART Map for Precision Medicine

Needs, challenges and opportunities

According to the experiences collected during the Industrial Dialogues and the Pilot, the responsible advancement of Precision Medicine depends on the capacity to build an ecosystem around the following domains:

A) <u>Data access and control</u>

The access to medically relevant data and control of their use are (well-known) top priorities in this field: building innovative solutions to address these challenges, which involve multiple actors, would offer opportunities to integrate many RRI principles. A participative approach (such as open platforms or software for dynamic consent) is essential to design new regulations and policies for data sharing and to strengthen medicine as an evidence-based practice.

B) <u>Standardisation</u>

The standardization of health care management is closely connected to the previous point, in order to ensure quality of services and products, but also improve the regulation of genomic medicine and provide integration of data according to shared principles. There is an opportunity to create new open standards, based on principles of responsible innovation.
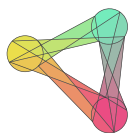
C) <u>Healthcare transformation & participative and multi-stakeholder processes</u>

The main drivers of healthcare transformation are the improvement of patient experiences and the shift towards a preventive medicine. The latter implies a participative approach to healthcare, which is at the core of RRI. It requires more coordination across the involved stakeholders and implementing participative approaches leading to stronger empowerment of patients and citizens, including stronger role for them in science (citizen science). The internet offers new opportunities to realise these goals by offering new instruments for data control and new forms of participation in all aspects of the innovation process.

D) <u>Building trust</u>

Defending privacy and transparency in the handling of sensitive medical data while at the same time building trust in data handling procedures and infrastructures is another top priority for all involved stakeholders. This includes avoiding excessive claims and promises

from research findings, and investing in transparency in private and public organisations at all levels.

E) Creating capacities and education

There is no implementation of RRI without creating the capacities for this transformation. Professionals in all areas should be trained and supported by RRI experts and intermediaries to read their field from an RRI perspective, especially when venturing into involving new stakeholders and building trust to create engagement. Identifying how to target specific challenges through an RRI approach requires know-how on how to interlink specific needs, ideas and opportunities to RRI practices and principles. More initiatives – also addressed to civil society and media professionals - are needed to create a shared language and to consolidate dissemination and participatory practices.

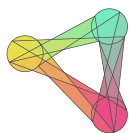## Societal Mobilisation and Advancement of Responsible industrial Technologies

One of the objectives of SMART-map is to design a flexible RRI approach to be implemented in the industrial innovation processes. Insights from the inclusion of a wide range of societal actors and the co-design approach used to craft this SMART Map suggest a number of framework conditions, which are the societal mobilisation goals we need to aim at, in order to allow the advancement of responsible industrial technologies.

1) The need to approach RRI as an ecosystem

While this project focuses on industry, any RRI approach requires the involvement of a large number of different players. The interaction of these players at all levels of the innovation process, through appropriate instruments for co-design, inclusion and participation, become a central element for the implementation of RRI. The adoption of principles of RRI governance, such as those described by ResAgorA Responsibility Navigator[11] should be considered fundamental.

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[11] http://responsibility-navigator.eu

2) <u>The need to establish framework conditions</u>

Responsible Precision Medicine in industry requires the implementation of standards and certification processes which induce organisational and cultural transformation. The legitimacy they grant incentivises compliance; they also trigger review and assessment procedures which involve multiple stakeholders. Additionally, it is important to introduce incentives and rewards for the adoption of RRI practices, include them as condition to access public funding, as well as add them as an element of the evaluation for career progressions.
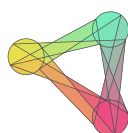
3) <u>The need to invest in communities</u>

There is a clear need for virtual and physical meeting places, to foster cross-stakeholder collaboration and build communities who practice RRI. Local institutions play a pivotal role to invest in such meeting places.

Actions for the Implementation of Responsible Innovation in Precision Medicine

The above described needs, challenges and opportunities represent the starting point in our roadmap, i.e. the key highlights in the current scenario of Precision Medicine, as emerged during the Industrial Dialogues and confirmed during our Pilot. Similarly, the societal mobilisation goals can be identified as the end point of our roadmap, i.e. where the multi-stakeholder activities believe the sector should go. Our experience therefore suggests some actions each stakeholder should implement, to tackle the current scenario and help moving Precision Medicine towards our goals.

The following list does not have the ambition of being exhaustive, as it is the result of two Industrial Dialogues and one company Pilot: nevertheless it indicates a few steps we believe crucial to implement RRI in the industries of Precision Medicine.
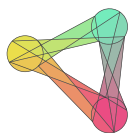
Action	Description	Who
PM1	Adopt multi-stakeholder approaches as standard practice to exchange information across the whole innovation cycle, to identify new business opportunities and anticipate market trends	Industry
PM2	Involve as many employees as possible, from different areas, into multi-stakeholder interactions, through adequate formats and training activities, as a way to cultivate a culture and sensitivity to RRI practice	Industry
PM3	Play a role in the institutional recognition of all professional figures actively involved in the RRI stakeholders network	Industry
PM4	Facilitate and contribute to improving doctors-patients interaction, by producing tailored communication and training materials, clinical decision aids and knowledge sharing	Industry
PM5	Identify a person responsible for RRI implementation in the senior management, and in each different areas of the company	Industry
PM6	Introduce RRI elements within the standards which apply to the company's products and services, and apply RRI practices to define them.	Industry

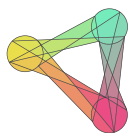| Action	Description	Who
PM7	Dedicate specific financial actions to support the participation of organisations (particularly CSOs) to multi-stakeholder initiatives in their communities and networks	Funders
PM8	Progressively introduce the involvement of a diverse group of stakeholders as well as the integration of RRI practices in innovation activities, as requirement for innovation grants	Funders

Action	Description	Who
PM9	Strengthen a multi-stakeholder (on top of multi-disciplinary) composition for grant evaluation panels	Funders

Action	Description	Who
PM10	Establish forms of professional recognition for all the professional figures playing a key role in the implementation of RRI in Precision Medicine	Policy makers
PM11	Introduce RRI training and multi-stakeholder practices at all levels of policy making, particularly with the aim of improving the patient experience	Policy makers
PM12	Promote (physical and virtual) public spaces to generate opportunities and facilitate the interaction of all stakeholders involved in the innovation of Precision Medicine	Policy makers
PM13	Introduce the participation to RRI practices as part of the evaluation criteria for career advancement	Policy Makers
PM14	Promote the inclusion of RRI methods within the standards of industrial products and services, as well as transparency and participatory approaches in the definition of standards	Policy Makers
PM15	Develop and discuss new participatory methods and tools for data access and data control	Policy Makers

Action	Description	Who
PM16	Dedicate more resources to the active participation to initiatives involving civil society into industrial innovation cycle	CSOs
PM17	Elaborate and advocate for processes aimed at shared governance of healthcare institutions, in order to better integrate patients experiences	CSOs