SMART·map

RoadMAPs to Societal Mobilisation for the Advancement of Responsible industrial Technologies

A SMART Map for Precision Medicine

Executive Summary for **Industry**

The SMART Map is a **tool that helps businesses** address issues of **social** and **environmental responsibility** they face in their innovation processes. It is based on the **Responsible Research Innovation (RRI)** approach promoted by the European Commission and it provides different stakeholders with practical suggestions on how to promote and put into practice these principles.

The SMART Map proposes **a route that guides industry** from the *current scenario of Precision Medicine* towards the *implementation of RRI practices* and their *potential benefits for companies*, through a series of *suggested actions* and concrete examples collected during a pilot.

Current scenario of Precision Medicine — *Suggested actions* — *Implementation of RRI practices* — *Benefits*

RRI: why you need to get there

RRI practices in the Precision Medicine industrial context have benefits at various levels for the industry sector

- For a **Chief Technology Officer**: when you carry out a technology assessment or need to update your product roadmaps, SMART-map tools can help you gather higher-quality input and run the exercise in a more customer-focused manner. Tools like an ***end user advisory panel***, or a ***multi-stakeholder responsible innovation group*** can offer independent views on what is important for your market, and support in anticipating trends. *"This kind of instruments helped us understand which will be the needs and barriers of physicians with less experience who are addressing genetic testing for the first time. It helps us anticipate and address their needs."*, said M.Carmen Álvarez, the IMEGEN Project Manager involved in piloting the tool.

- For the **R&D and Product Development**: SMART-map tools can help translating the company vision into requirements for R&D process, and implement "agile ways of working". ***Co-creation multi-stakeholder groups***, as well as ***end-user advisory panels*** and ***participatory feedback tools***, can enable greater patient-centricity and can help rapid prototyping and agile design. ***RRI workforce training*** help staff understanding and making the best use of external ideas. *"Waiting for the test results without any information in the meanwhile is pretty difficult"* reported one of the patients involved in the pilot. It is also for this reason that IMEGEN is considering introducing more material targeted to patients, and potentially an online tracking tool.

- For **Commercialisation and assessment**: SMART-map tools can help addressing gaps in health technology assessment, and particularly in patient-reported outcomes, to know better their audience and prepare for regulatory approval. ***Repositories for subjective experience of treatments*** can help comparing patient experiences with the view or needs of other stakeholders; ***RRI standards and accreditation***, including labelling of the product, will help commercialising activities. ***Living labs*** and ***end-user advisory panels*** can help gathering information for regulators. One of the patients involved in the pilot stressed that *"psychological care, as well as a comfortable environment where the results are communicated face-to-face are really important to understand and deal with the conclusions of diagnostic report"*, highlighting the transformative potential of collecting these feedbacks.

RRI: how you get there

A list of suggested actions the industry sector could implement to help moving Precision Medicine towards RRI

1. Adopt **multi-stakeholder approaches** to identify **new business opportunities**
2. **Involve as many employees as possible** into multi-stakeholder interactions, through adequate **training activities**
3. Play a role in the **institutional recognition** of all professional figures actively involved in the **RRI**
4. Contribute to **improving doctors-patients interactions**, by producing **tailored communication and training materials**
5. Identify a **person responsible for RRI implementation** in each different areas of the company
6. Introduce **RRI elements within the standards** which apply to the company's products and services

Needs, challenges and opportunities for RRI

Key highlights in the current scenario of Precision Medicine

- **Data access and control**: : building innovative solutions related to the access to medically relevant data and the control of their use, such as open platforms or software for dynamic consent
- **Standardisation**: ensuring the quality of services and products; improving the regulation of genomic medicine; creating new open standards
- **Healthcare transformation & participative and multi-stakeholder processes**: facilitating coordination across the stakeholders; implementing participative approaches that lead to stronger empowerment of patients and citizens
- **Building trust**: defending privacy in the handling of medical data; avoiding excessive claims from research findings; investing in transparency in private and public organisations
- **Creating capacities and education**: training and supporting professionals to read their field in an RRI perspective; consolidating dissemination and participatory practices

Societal Mobilisation Goals

Where the multi-stakeholder activities believe the sector should go

- **The need to approach RRI as an ecosystem**: it is essential to build and maintain interactions among different players at all levels of the innovation process.
- **The need to establish framework conditions**: it is pivotal to implement standards and certification processes as well as incentives and rewards that could promote RRI practices.
- **The need to invest in communities**: there is a clear need for virtual and physical meeting places, to foster cross-stakeholder collaboration and build communities who practice RRI.

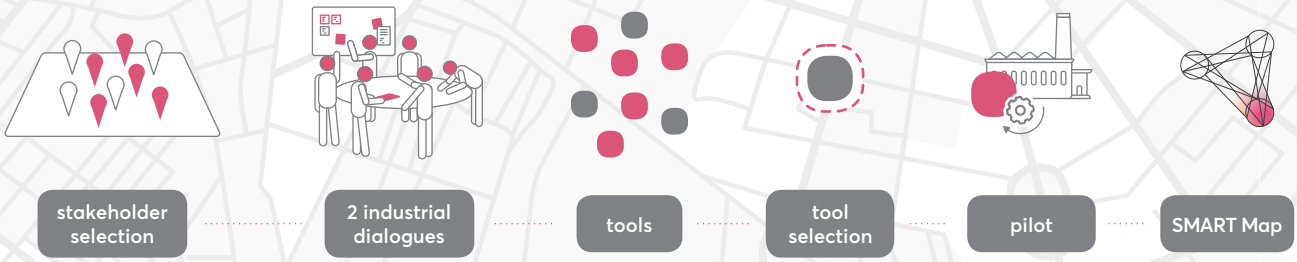
How the SMART Map has been drafted

The SMART Map is the outcome of a process that began with two workshops, the ***Industrial Dialogues***, that took place in **Aarhus** (Denmark) and **Valencia** (Spain). A broad range of stakeholders participated in the workshops and produced a number of proposals of RRI Precision Medicine toolboxes.

One of the toolboxes has been tested at **IMEGEN**, a Spanish SME specialized in genetic studies and partner of SMART-map.

The Aarhus and Valencia Industrial Dialogues

37 participants
16 actors from the Industry sector
5 Civil Society Organisations
3 research institutions
6 complex toolboxes co-designed by participants



The pilot phase: testing one of the RRI toolbox in the Precision Medicine industrial context

The tool:
End-user Advisory Panel
Pilot organization:
IMEGEN

imegen

IMEGEN has tested the introduction of an **end-user advisory panel**, which involved patients and doctors and was aimed at experimenting a new approach to a product they are launching on the market. The product is a genetic diagnostic service used to sequence the coding part of the genome. Based on the pilot experience, the company has elaborated **eight concrete actions** that address important needs and expectations in terms of **awareness**, **training** and **communication**.