Helping companies grow their business with Responsible Research and Innovation: example scenarios.

In precision medicine patient-centric and doctor-centric approaches are understandably key to success in the field, but the complexity of this sector requires the understanding and the involvement of multiple stakeholders: SMART-map has identified a number of tools to help companies achieving this goal and thus developing successful value propositions, not just by tackling users' needs but addressing also their values in a broader society-oriented vision.

One of these tools has been selected for a pilot within a company, Instituto de Medicina Genomica S.L. (IMEGEN), founded in 2009 as a spin-off of the Genetics Department of the University of Valencia. The company has specialized in the diagnosis, prognosis, therapy and prevention of human diseases mainly by the development of diagnostic/pharmacogenomics tests and also provides services for Genetic Testing to Hospitals, Clinics, laboratories and Companies according to high quality standards. IMEGEN is developing exome sequencing diagnostics as a new product, with the potential of targeting both specialised medical / hospital markets but also considering direct to consumer genetics. The selected tool was applied to the early phase of design of this product.

In the following pages some example scenarios, of how some of the tools might help your business.

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Scenario 1: Chief Technology Officer or Head of Marketing

The Chief Technology Officer[1] typically has the mandate to assess new technologies for the company and/or evolve the current product roadmaps – often within a 5-10 year timeframe. Naturally, this is not an easy task as knowledge about new technologies is either completely absent from the organization or resides only in small (often unknown) pockets of the organization. In addition, perspectives about technology are usually anchored in the status quo and technology assessments can be biased by current organisational beliefs or interests.

If you are tasked with another technology assessment or with updating product roadmaps, SMART-map tools can help you gather higher-quality input and run the exercise in a more customer-focused manner: the responsible research and innovation approach is about engaging society while integrating a framework of different dimensions, which helps understanding better the sustainability, the acceptance as well as positioning of your products.
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, both in terms of technology but also needs to be addressed. Implementing RRI methods has the added value of understanding the impact of technology from different perspectives at the same time, and to better capture external ideas, their dynamics, and establish new approaches of knowledge sharing. Including different stakeholders and focusing on a set of dimensions for the exercise helps needs and new technologies to address them to emerge: critical information for an improved technology assessment.

For example, during our pilot in IMEGEN a panel composed by patients and doctors highlighted the increasing need for re-analysis of genomic diagnostics results, as a consequence of the evolving knowledge about the clinical actions associated with different genetic profiles. The company will be using this information to plan their technology

[1] or the Head of Innovation or Marketing, or Global Product Manager in some companies

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roadmap and infrastructure, in order to account for the storage needs, data access issue, updating reports, and potentially new products and services in this area.

Many other inputs emerged from this work: “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. Key opinion leaders often have a significant influence in the design of a product, and healthcare companies find it difficult to understand the need of a broad range of users: our experience shows how integrating RRI can help filling this important gap.

Our SMART Map contains several additional examples of tools and methods you can apply, with the ultimate benefits of improving your roadmaps and identifying new business opportunities.

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Scenario 2: R&D

R&D and Product Development processes are typically highly structured, ranging from 5-20 process steps that can take up to 15 years between idea and product launch for the pharmaceutical industry. While many pharmaceutical and MedTech companies propagate "patient-centricity" as the vision for their company, surprisingly few companies have translated this vision into requirements for the R&D process. For example, the technical development organizations of pharma companies typically design both size, shape and packaging of new drugs. However, these organization rarely have direct interactions with patients. Often, they rely on traditional surveys and focus groups that are managed and set up by colleagues from other parts of the organization.
Furthermore, there is increasing interest in "agile ways of working" in pharma and MedTech R&D as companies feel that their scientific staff spend a disproportionate amount of time on documentation and administrative tasks. Breaking through administrative complexity requires tools and new ways of working: Co-development of solutions together with physicians and patients is a powerful antidote to internal bureaucracy. After all, if physicians and patients need a new solution or a new feature, this is "powerful argument" vs. internal bureacracy.

SMART-map tools that can enable greater patient-centricity and agility are ***co-creation multi-stakeholder groups***, as well as *end-user advisory panels*, but also different types of ***participatory feedback tools*** which can help rapid prototyping and agile design. Different methods for ***RRI workforce training*** help scientific and technical staff understanding and making the best use of external ideas, interacting with different stakeholders in the most productive way, as well as viewing the products they develop in a larger perspective of usability and sustainability. Tools for ***multi-stakeholder data sharing*** also strengthen knowledge sharing practices and increase external input.

During our pilot in IMEGEN for example, the end-user panel discussed the design of the diagnostic report which delivers the results of the exome diagnostics product, and the company introduced some changes in the design, based on the feedback received by both doctors and patients. At the same time, the need for accompanying material directed to patients was identified, allowing the company developers to plan additional communication collaterals to be delivered together with the product.

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"The reasons for choosing a specific test and provider are mostly based on the trust given by the scientific team to a specific company" said some of the doctors in the advisory group during the pilot. "Waiting for the test results without any information in the meanwhile is pretty difficult" reported one of the patients. It is also for this reason that IMEGEN is considering introducing more material targeted to patients, and potentially an online tracking tool.

Overall, the suggestions described in our SMART Map will help propagating a patient-centric vision through the organisation, and improve existing design methodology as well as your products.

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Scenario 3: Commercialisation and Assessment

As new products get closer to launch, complex dynamics play out for pharmaceutical and MedTech companies. In essence, each company needs to cater to the needs of at least 4 audiences: the regulator, the payor, the prescriber, the patient. Naturally, it is often impossible to find the perfect solution that equally satisfies each audience.

As a product reaches the later stages of R&D, the regulatory audience typically is top of mind. After all, an R&D organization is usually incentivised to get new products to market and the regulatory authority is the "gate-keeper" towards achieving this goal. However, there are some interdependencies: for example, regulators have become increasingly interested in the patient perspective in recent years, so knowledge about patient needs and how patients perceive the new product/solution can play an important role for regulatory approval.

In most pharmaceutical companies, market access and reimbursement considerations have been woven into the R&D process. After all, why would you develop a product over 10-15 years if there won't be reimbursement in the end? Reimbursement, however, is often linked with health technology assessments (HTA). In several countries, HTAs are looking at benefits vs. the existing standard of care and/or cost effectiveness calculations on the basis of the effect of the new product. Interestingly, most HTAs also look at patient-reported outcomes (PRO), a category in the assessment that traditionally has been left "blank" by many companies.

Of course, physicians are interested in the therapeutic effect and the side-effects of the new product/solution. However, they are also interested in how prescription of the new product or service is going to "fit" with the daily routines and way of working in their hospital or practices. There have been quite a few new products (e.g., the new generation of anti-coagulation medicines) where there have been questions how these new drugs will change examination routines for physicians.

Finally, patients have become more interested in their health, disease and the management of both. Frequently, patients come to the physician office with a stack of printouts from their "internet search". And patients increasingly link up among themselves, sharing perspectives on benefits and down-sides of medication, but also their effect on daily lives. Naturally, what is important for patients is not necessarily the same for patients compared with the other stakeholders. For example, an important "treatment outcome" for psoriasis patients can be that they feel comfortable wearing a dress or shorts during summer, something they often

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avoid in light of psoriatic skin plaques.
In summary, it is paramount for pharma and MedTech companies to "know their audiences" as they prepare for the regulatory approval, reimbursement negotiations and product launch.

SMART-map can help during this process with a number of tools that are designed to bring together this different number of audiences, and use their interaction to collect a wide range of inputs. The approach of Responsible Research and Innovation embedded in these tools maximises the chances to capture different perspectives, thus offering a more complete view of sustainability, impact and feedback on the product, as well as more customer-oriented ways to communicate, package and deliver. ***Repositories for subjective experience of treatments*** can help comparing patient experiences with the view or needs of other stakeholders, but also provide new approaches for collecting patient-reported outcomes; the definition of ***RRI standards and accreditation***, including labelling of the product, will help commercialising activities. ***Living labs*** with different formats as well as ***end-user advisory panels*** can help gathering the information regulators are increasingly interested into, by bringing together both patients reported information and the physicians' perspective.

During the pilot we conducted in IMEGEN, the end-user advisory panels has identified a number of key patient-reported outcomes, particularly related to the access to the diagnostic product, to the improvement of their diagnostic journey especially during the time they wait for results to be delivered, as well as areas where the company could facilitate the doctor-patient counselling process and therefore the patient experience associated to the product.

"Multi-stakeholder tools are a valuable resource to define priorities that the company's external communication should address", highlighted Mari Carmen Álvarez, IMEGEN Project Manager, while one of the patients involved in the advisory group 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"

The use of tools like the ones included in the SMART Map has shown how they can help increasing the awareness about the audiences of the product, and contribute to key aspects of the product launch and communication.

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