Over the past year the Dutch Ministry of Economic Affairs & Climate and the Dutch Entrepreneurship Agency together with the EU Commission have facilitated a number of events to align stakeholders to collaborate on tech entrepreneurship for sustainable innovation: high tech solutions that drive economic, societal and business value.

The development, implementation and scale-up of these solutions strongly depends on contextual circumstances such as digital readiness and (business)model transformation. These circumstances are determined by the conditions set by multiple stakeholders across the chain from tech product to new market solution. A challenging landscape to navigate not just for the tech solution providers but for all stakeholders involved in establishing new eco-systems for sustainable innovation.

To align the perspectives of stakeholders in order to create transparency and provide tailored guidance to all stakeholders on their journey the Valuetracking method has been applied. This method facilitates collective investigation through stakeholder feedback loops and enables multi-stakeholder collaboration to build-up an inclusive digital compass for sustainable innovation in an iterative way.

**FOCUS ON HEALTH AND REGULATION**

Often the medical device regulations are studied rather late in the innovation process. Innovators get a chance to excel in regulatory compliance early on and turn it into their competitive advantage. To build success stories, we need to make the local companies, university innovators, investors and related stakeholders more educated on topics, that may be overwhelming for the non-expert, but crucial for making business. In maintaining a well organised health innovation ecosystem, keeping all stakeholders well in the loop, the regulatory compass helps greatly in sharing knowledge efficiently to the ones in need.

During a number of global hybrid sessions over the past months, the Valuetracking approach* has been applied to facilitate multi-stakeholder collaboration in order to accelerate sustainable innovation. A common threat was realised for a dynamic network of global Innovative Healthcare experts to collectively invest common value, constraints & conditions and to define their focus to collaborate. Together they established the aim for the call-to-collaborate:

**Setting up the building blocks to realise the regulatory compass for innovative healthcare**

**AMBITION**

Our ambition is to free up the road for a growing number of life altering break throughs that drive sustainable health innovation by facilitating med tech entrepreneurs to better and faster navigate the complex regulatory landscape. Through the Regulatory Compass we turn piles of regulatory requirements into minutes of clarity and instant actionable knowledge.

Accomplishing the goal of the Regulatory Compass for Health Innovation means that entrepreneurial med tech providers will be far better equipped to face regulatory challenges and have an increased chance to evolve into viable companies.

As a consequence, the compass will also function as a feedback loop to investigate real-life business and market development constraints and conditions. And as such the collective gain is that valuable insights can be shared with all stakeholders tailored to their role in the chain from tech product to global market solution.

**Valuetrack scope**

Following the Valuetrack method first the **Collective Value Case for Innovative Healthcare** has been validated based on economic, societal and business value.

Consequently the analyses on business development **constraints** and market development **conditions** showed that regulation is recognized by all stakeholders as a common challenge.

As a result **stakeholders have prioritized a call-to-collaborate** focusing on EU Medical Device Regulations to integrate in the Regulatory Compass for Healthcare Innovation.

Over the past few months the Minimum Viable Product has been developed for Medical Device Regulation. The format enables broader implementation though.

**In parallel a roadmap will be defined to consequently add on the General Data Protection Regulation and the In-Vitro-Diagnostica**.

Also relevant stakeholder profiles have been defined to effectively engage more stakeholders to participate in the **call-to-collaborate to further develop the compass.**

**THE REGULATORY COMPASS**

*BOTH TECH INNOVATORS AND STAKEHOLDERS BENEFIT*

The compass turns regulatory contents into a flow that indicates to what measure you (have to) meet regulatory requirements in line with your specific product. It provides clause by clause references and links to the original requirements based on the specifics of each product. And it presents the terminology, examples and guidance from the regulatory sources in an intuitive format whilst an audit trail with complete references will be generated.

Key benefits are:

An effective instrument as a rationale for the med tech provider to dive into the development and implementation of a product aligned to the context of it's (potential) market.

Reflection on the compliance cycle from legal framework to policy. The audit trail that builds up automatically also provides a head start when looking for the right advisor to further investigate.

Early warning to inform users upfront on upcoming changes is the alert system to ensure they can be better prepared and support their decisionmaking.

Registration of users and their audit trails can be captured anonymously to gain relevant insights for all stakeholders involved.

**ROADMAP H2 Y2022**

Resarche

What are the typical elements of the tech solutions and their providers to define / tailor the dialogue?

What information should be processed in the management dashboard?

In what way can stakeholders be aligned and participate in the integrated dialogue?

What is the roadmap to integrate further regulation such as IVDR and GDPR?