



## D2.8: COUCH Participatory Innovation Process

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- Danish Board of Technology Foundation (DBT)
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- University of Dundee (UDun)
- Universitat Politècnica de València, Grupa SABIEN (UPV)
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## Abstract

In this report the approach, method, findings and concluding reflections on the collaborative approach to responsible research and development developed and carried out in the Council of Coaches project are reviewed. The report provides a short theoretical background for the project and situates it in context. Our RRI approach is explained as concept and as a construct in the making, where the empirical findings and learnings contribute to the final concept of the method. Also, the report presents a representative sample of the multifaceted material provided by our socio-technical integration process and engagement with stakeholders and users.

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## Symbols, abbreviations and acronyms

CMC	Centre for Monitoring and Coaching
COUCH	Council of Coaches
D	Deliverable
DBT	Danish Board of Technology Foundation
EC	European Commission
ISPRINT	Innovation Sprint
M	Month
MS	Milestone
RRD	Roessingh Research and Development
RRI	Responsible Research and Innovation
SU	Sorbonne University
UDun	University of Dundee
UPV	Universitat Politècnica de València
UT	University of Twente
WP	Work Package

# 1 Introduction

In the Council of Coaches project, RRI-work on ethical, social, and legal considerations and implications has been developed, carried out and fed back into technical, product and process development of research and project work from the very outset. This report describes the background, methodology and design, along with the practical empirical work and findings of our process of identifying, working with, and keeping a focus on the core responsibility issues in the Council of Coaches project.

## 1.1 Concern and scope of this report

In the Council of Coaches project, the RRI-process has been the simultaneous movement of carrying out the concrete RRI-work, fulfilling the tasks agreed upon in the RRI Vision (D2.1) while also developing a genuine method for arriving at project-specific, hands-on RRI solutions. The main task of the RRI-team has been to keep the project focused on pertinent issues and to stir reflection and debate within the project to solve them in the best possible way.

In the concluding deliverables of WP2, **D2.7** and **D2.8**, the RRI-issues, the RRI-process itself and the context of the endeavour is reviewed. For clarification of the structure: D2.7 and D2.8 are complementary; in D2.7 the four core RRI-issues for the Council of Coaches project, their development throughout the project period and the work carried out to handle them is described in further detail, while the purpose of the report currently at hand is to cover the 'everything else' of the RRI-work. Hence this report outlines **the background, methodology and design** of the RRI-work carried out in the Council of Coaches project along with **an overview of the empirical socio-technical integration process and the core findings**.

## 1.2 – and then COVID-19 came along...

In the design of our process and tasks, we have been very aware that due to the novel and experimental character of our approach it would not be a one-size-fits-all approach. This was reflected in the schedule and planning of the RRI-work as well as in the flexibility of the RRI-workshops we have arranged following the technical integration events (hackathons) held by the consortium, where partners spent a week at a time building and programming the platform together. At these meetings, the RRI-team would usually come by mid-week and braid RRI-related reflection exercises into the themes of the hackathons, as the exact purpose of the exercises was, in addition to addressing RRI-related issues head on, to develop an general RRI-conscience among the researchers in order for the responsibility thinking to settle in the outlook of the researchers so that broader societal dimensions of their work will always henceforth be a component of their everyday work and decision making. Thus, while having an overall time plan for our internal social integration work as well as its relation to external RRI-events such as the stakeholder engagement process (T2.2) and the RRI-relevant user interactions (in T2.3) we decisively led the themes of the exercises follow the empirical developments of the project work at the time of the hackathons leaving much space for tailoring adjustments for a close empirical fit while making everything work in unison to fulfil our overall masterplan. However, there was one empirical event we had not prepared for, and that was when the COVID-19 came along.

For the Council of Coaches' RRI-process the pandemic and the ensuing close-down of Europe in the spring and summer of 2020 had the direct effect that we had to postpone and ultimately convert our third interactive and participatory Stakeholder Workshop (T2.2 originally planned for March 2020) to an online format launched in May 2020. We had hoped to create an inspiring environment for open debate and with plenty of space for networking much like the inspirational exchange carried out in our second Stakeholder Workshop in February 2019, but as the travel ban put a full stop to all considerations of that kind, we needed to adapt to the situation. Changing our workshop to an online event meant that we had to renounce on the usual naturally occurring spaces of networking and personal chemistry-generated off-the-grid context that participants will provide you with during coffee breaks etc. However, in a certain sense we gained on the roundabouts what we lost on the swings, in that the online format released the event in another sense and made it possible for people to participate that would not have been able had they had to travel to another country to do so, and we ended up having a nice representation from the sectors and interested parties (consortium, industry, care providers, health professionals, policy-making

and government, civil society and patient organisations) that we had hoped for as well as a fruitful exchange and outputs for the last phase of the process.

## 2 Background

In the following a short background for the framing of the RRI-work in the Council of Coaches project is outlined. The format of the RRI-process had the overall purpose of supporting the design and innovation work in the project as well and empirically close as possible. Therefore, the process needed to be pieced together in a way that considered the particular nature of the project's content and concerns as well as the state-of-the-art in RRI-thinking responding to the original call text.

### 2.1 Concerns specific to mHealth and virtual coaching

WHO's Global Observatory of eHealth (GOe) defines mobile health (mHealth) as

*"medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"*

From the beginning of the project, the Council of Coaches consortium has been well aware that there may be particular ethical concerns linked to the development and implementation of devices in the area of mHealth that go beyond the concerns linked to eHealth and healthcare in general, for example has mHealth been argued to be able to potentially alter the practice of healthcare and patient-physician relationships as well as how bodies and health are being represented. Also, the use of virtual coaches in itself may be a line of work that requires heightened ethical responsiveness, not least in fields where the user segment consists of vulnerable subjects who may not be able to navigate issues of consent or trade-offs between reality and fiction as readily.

In the RRI Vision document (D2.1) relevant sources for an RRI-related overview of important principles are identified. Throughout the RRI-process these principles have been supporting the reflection and exercises carried out. The most important principles are outlined here, for a full review see D2.1.

In the area of mHealth, the main inspiration has come from Albrecht & Fangerau, 2015, who reviews the so-called 'Georgetown mantra', the four principles typically cited in codes of medical ethics, for mHealth. These principles are **autonomy**, **beneficence**, **non-maleficence**, and **justice**. According to Albrecht & Fangerau these principles still apply to mHealth applications, although their concrete implications are new. They provide us with the following remarks on specific concerns to be considered by mHealth developers seeking to ensure ethical development and implementation:

**Table 1: Specific concerns to be considered by mHealth developers.**

Adapting medical ethics to mHealth	
<b>Autonomy</b>	<ul style="list-style-type: none"> <li>Respecting the right to self-determination with respect to active or passive participation, use or application of mHealth are concerned</li> <li>Voluntary participation and the right to withdraw at any time</li> <li>Comprehensive and target-group as well as situation specific information must be provided to allow an informed decision</li> <li>Promotion of health awareness for (self-) confident decision making in health contexts</li> </ul>
<b>Beneficence</b>	<ul style="list-style-type: none"> <li>The primary benefits for the affected persons must be obvious or deducible</li> <li>The objectives must be achieved based on valid data</li> <li>Decision processes must be transparent and need to include all stakeholders concerned (affected persons) in order to justify an intervention in a comprehensible manner</li> </ul>
<b>Non-maleficence</b>	<ul style="list-style-type: none"> <li>The mHealth intervention shall not in any way have a negative impact on its user or on the receiving party. Specifically, this applies to the physical and mental wellbeing of each individual, a group of individuals or the individual's environment.</li> </ul>



	<ul style="list-style-type: none"> <li>▪ The risks of an intervention must be commensurate with its expected benefits.</li> <li>▪ This requires carefully weighing up the risks and benefits based on valid and reliable information.</li> <li>▪ The right to privacy, which, aside from confidentiality also includes protecting personal integrity, must be protected in order to prevent any harm.</li> </ul>
<b>Justice</b>	<ul style="list-style-type: none"> <li>▪ mHealth interventions must be available to everyone, regardless of social status, income, education, political orientation, religious faith, inclinations and ideals, gender, age, ethnic group but also when it comes to technical affinity, health competence, mental or physical impairments. Neither discrimination nor stigmatisation may be caused by the intervention.</li> <li>▪ mHealth interventions should aim at eliminating existing inequalities. For this, the fair distribution of potential benefits and potential harm within the target group is a prerequisite.</li> </ul>
<b>Good Science Practice</b>	<ul style="list-style-type: none"> <li>▪ Research is necessary to generate valid and reliable data. For all research, the commonly known principles of good scientific practice as well as the biomedical principles of research must be respected.</li> </ul>

In the area of virtual coaches, we have been very inspired by a broad assessment of the potential impacts of virtual coaching carried out at the Rathenau Institute (Kool, Timmer, & Van Est, 2015). The authors argue that responsible development in the field of virtual coaches must be ensured through ongoing interaction between a number of different actors, such as research groups, patient groups, product developers, the health sector, and state regulators (*ibid*). For ensuring the quality of a virtual coach-approach the authors recommend adherence to the following principles:

**Table 2: Recommendations for ensuring the quality of virtual coaches.**

Potential impacts of virtual coaching	
<b>Professional seal of approval</b>	Consumer organisations and app developers should reach agreement on quality criteria for e-coaches. Consumers need information about what the e-coach does and on what information the e-coach comes to its advice.
<b>Guarantee privacy</b>	The stricter privacy legislation that is on the horizon imposes more stringent requirements on product developers. Product developers and governments need to prepare now for those requirements and work diligently on protecting privacy.
<b>Respect autonomy</b>	The e-coach influences the user in order to bring about a change in his/her behaviour. Providers of e-coaches should therefore be compelled to make clear what techniques of persuasion the device is using.
<b>Government bears the burden of proof</b>	Government can only make the use of an e-coach mandatory if it first demonstrates that doing so is justified.

<b>Transparent revenue models</b>	Users of e-coaches now deal with a network of parties, each of which has its own (commercial) interests. The user's interests are not always automatically the top priority. The Rathenau Institute calls on regulatory bodies to investigate the revenue models used for e-coaching applications. Governments should also make it mandatory for providers to be transparent about their revenue model.
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In the context of the Council of Coaches, we have taken the recommendation to base our work on an open exchange with multi actors close to heart. This is reflected in the design of our stiRRIng process, which is covered in chapter 3.

## 2.2 The responsibility agenda: Objectives of RRI-method development in COUCH

One of the integrative new features of the RRI method developed by the Council of Coaches is the co-creative process of settling the array of issues of particular concern for the project to keep in focus. Rather than inducing or deducing such a list from either going minutely through the Horizon 2020 RRI objectives, the keywords of the call in which the project has originated or a comprehensive, quantitative interpretation of everything that might arise during the project period, the Council of Coaches has chosen a different path. We wanted to target the qualitatively most critical issues as seen from inside the consortium – the consortium in total – and to develop the RRI process from the intention to instill ownership and commitment to keeping these issues a vital part of the project's technical development and at the center of innovative decisions all the way through the project. This is where the framing of the RRI Vision began – by creating a collective process and space for dialogue where reflection could unfold together with a shared commitment and intention throughout the consortium to maintain creativity and dedication in relation to handling the issues in the best possible way. The responsibility agenda was at once a shared consideration and a distribution of responsibilities, as the nature of each of the appointed issues at the same time indicated which of the partners should be primarily responsible for steering the issue in the desired direction. In a carefully orchestrated process involving outside stakeholders and multi-actors from research, patient groups, industry, product developers, the health sector, and state regulators, we aimed for a comprehensive interplay between deep, internal project-specific up-to-the-minute accounts from the consortium and broader debated and perspectives from outside positions.

The specifics of the co-creative process leading to the formulation of the RRI Vision is described at further length in chapter 3 and the developments of the designated issues throughout the project is the topic of D2.7. The designated RRI issues that we have worked with throughout the project are:

Four primary issues:

**Issue #1: Privacy and informed consent**

**Issue #2: Trust (not too little, not too much)**

**Issue #3: Handling disagreement between coaches**

**Issue #4: How to keep healthcare knowledge up to date?**

And in addition to these, eight boundary issues consisting of:

**Issue #5: Intrusion**

**Issue #6: Personalisation**

**Issue #7: Consistency/honesty**

**Issue #8: Privacy by design**

**Issue #9: Illegitimate exploitation**

**Issue #10: Economic vs health incentives**

**Issue #11: Equality**

**Issue #12: Liability**

With the content clarified we will now take a leap in time in abstraction and review the methodology and design plan that lies behind the work carried out.

## 3 Methodology and design

### 3.1 Three interlaced processes of learning-by-doing

The overall design of the RRI process was developed in an explorative and processual format with a number of essential objectives in mind. The process needs to ensure that research and innovation carried out in the project adhere to the principles of Responsible Research and Innovation, implementing the framework laid out in the European Responsible Industry project (EU-FP7-609817). It also needs to ensure that the new tools and coaching methods, as well as the actual R&I processes in the project contributes effectively to the needs of future users and society at large, are aligned with societal values and ethical considerations, and have a realistic chance of succeeding in the competitive market of eHealth and e-Coaching tools. Achievement of these ambitions were envisioned to be obtainable through the following, interlaced processes (to be regarded as simultaneous activities rather than consecutive phases):

- Development of a shared understanding and vision of what RRI means for the COUCH consortium and how this vision should be achieved;
- Stakeholder and user engagement processes: a series of deliberative, co-constructive multi-stakeholder workshops;
- Socio-technical integration: social scientists engage scientists and engineers in semi-structured interactions designed to enhance reflection upon research decisions in light of broader considerations -including the stakeholder views -and societal implications.

The precise timing and content of the concrete workshops and activities of the above processes were not planned in detail as we wanted to tailor the empirical unfolding to follow other activities in the project as close as possible. We wanted to do this to obtain a close empirical fit between what was going on in the technical development and the innovation work, to tap into already ongoing creative processes and elaborate reflective work with RRI-related dimensions, and also to save time and money by making consortium-wide RRI-reflection follow already planned physical events.

Beneath a list of planned activities and their perceived interconnection at the beginning of the project:

**Table 3: List of planned RRI activities and their perceived interconnection.**

Type of activity	Participants and purpose	Approximate timing
1 <sup>st</sup> stakeholder workshop	Stakeholders, obtain input for the RRI Vision	M5
RRI Vision workshop	Consortium, agree on the RRI Vision	M5
1 <sup>st</sup> stiRRIng workshop	Consortium, reflective work on 4 main RRI issues	M7
2 <sup>nd</sup> stiRRIng workshop	Consortium, reflective work on secondary RRI issues	M8
3 <sup>rd</sup> stiRRIng workshop	Consortium, reflective work on workflows	M10
4 <sup>th</sup> stiRRIng workshop	Consortium, reflective work on 4 main RRI issues and desirable stakeholder inputs for stakeholder workshop 2	M12-17
5 <sup>th</sup> stiRRIng workshop	Consortium, reflective work on outputs from stakeholder workshop 2 and responsible exploitation	M14-19
2 <sup>nd</sup> stakeholder workshop	Stakeholders, inputs on 4 main RRI issues	M14-19
3 <sup>rd</sup> stakeholder workshop	Stakeholders, inputs on responsible exploitation	M24-33

In the following sections the methodological building blocks are elaborated and explained further

### 3.2 First process: Committing to a vision of responsibility

The first process had the objective of installing a framework for the operationalisation of RRI at project level, decide on the core RRI issues and work out a shared vision for handling these issues within the project.

The rationale for choosing a veritable hands-on bottom-up approach in this process has been the assertion that a co-creative effort of developing a shared understanding and vision of what RRI means in concrete terms for the project and how this vision should be realised has contributed significantly to induce ownership amongst the partners and accommodate project-specific requirements and conditions much better than a predesigned box-ticking format. The guiding event has been the RRI Vision workshop in M5, where the consortium through carefully facilitated deliberative and co-creative work has developed a shared understanding of RRI in the context of the Council of Coaches project and identified the most pertinent issues in relation to the forthcoming technical and innovative work

Concretely, the consortium, or at least one person from each of the partners, has met physically for a two-day workshop event. The first day was reserved for reflective processes and brainstorming broadly perceived, while the second focused on deciding on the most pertinent issues and how to design the concrete process keeping these at the forefront of concern moving forward. As preparation for the event, all participants have been provided with a background brief on the Responsible Research and Innovation framework in the EU and the challenges and difficulties involved in operationalising this framework at project level.

The output of the event has been a joint agreement in the consortium about how to make sure the Council of Coaches proceeds responsibly. It also doubles as D2.1 *The COUCH RRI Vision*.

### 3.3 Second process: STIR + RRI = StiRRIng; socio-technical integration as a navigation tool

The second process consisted of a tailored version of socio-technical integration work that we have adapted to fit the distinct conditions and needs of COUCH to support the integration of ethical and societal perspectives in the research processes conducted in the project. Since RRI cannot be reduced to a matter of compliance but must inevitably involve an element of open reflection in each consortium, we have sought to redeem and contain this process in an open yet structured format. We wanted to find a way to support the conversation inside the consortium with acting on and adapting to inputs from stakeholders and users in the identification and management of RRI issues in order to integrate their perspectives in the design and innovation processes. By expanding the methodological elements native to the European RRI discussion with an amended version of the Socio-Technical Integration Research (STIR) method (Fischer & Schuurbijs, 2013) developed by researchers at the University of Arizona, we feel we have found a suitable way to do so.

The STIR method came into being in the US as an attempt to respond to the increased demands on laboratories from science and technology policies to address broader societal dimensions of their work. Despite longstanding calls for collaborations between natural and human scientists to achieve this goal, neither the capacity of laboratories to respond to the demands nor the role that interdisciplinary collaborations may play in enhancing responsiveness was well understood or empirically supported. To overcome these limitations and to design, implement and assess effective programs aimed at responsible innovation, a work program in the form of an experimental platform was put together where scientists and engineers could incorporate the methods and perspectives of the social sciences and humanities, while going about their normal work. The main objective was to understand the conditions under which science and engineering research practices can be responsive to social and ethical concerns. This was done by a form of anthropological embedding where humanists (or other researchers with a profile enabling them to act as advocates of the overarching principles of responsibility) undertook prolonged outplacements (12 weeks) among laboratory scientists with the task to unpack the social and ethical dimensions of research and innovation in real time and to

document and analyse the results. During these embedding periods, the humanists interacted with the scientists via semi-structured protocols of interviews and interventions aiming to 'stir' up reflection about responsibility aspects of lab practices, e.g. animal rights, human rights, etc. (<http://cns.asu.edu/research/stir>)

What we have imported from this method is basically the overall rationale of ongoing interactions aiming to 'stir' up reflection about the practical implications of the RRI vision agreed upon by the consortium (hence the acronym StiRRIng). But since the Council of Coaches is carried out by a cross-European consortium with each partner having their own work routines and local conditions, lengthy outplacements with each of the partners was neither considered the most economically feasible nor perhaps the most impactful approach. To adapt the STIR method to these conditions, instead we have designed a blend of semi-structured interviews with individual researchers and mini-workshops to be carried out at consortium meetings and 'hackathons' to intervene in a collaborative, hands-on manner at strategic points during the development period, when the consortium is already brought together in a given location.

In practice, a number of RRI-workshops have been carried out, primarily within the first 1½ year of the project, where the RRI facilitators (WP2) have arranged condensed reflection exercises on the selected RRI issues and related topics and kept track of developments related to responsibility in the technical and innovation project processes. Content-wise the interactions have been guided by semi-structured interaction protocols specifically designed to enhance reflection upon research decisions in light of broader considerations and to support anticipation and responsiveness. They have also provided a process to adapt stakeholder involvements in desirable ways, so that consortium members can make sure that pertinent questions and discussions are brought to the table and integrated in preparation of the stakeholder events just as stakeholder inputs have been brought back to the consortium and debated in a thorough and elaborate manner. Socio-technical integration challenged consortium members to actively reflect on the potential outcomes of their work while it was being conducted, and to adjust their research practices and research directions accordingly.

### 3.4 Third process: The stakeholder and user engagement process

The third process consisted of a series of three interactive and participatory stakeholder workshops with the aim of better aligning COUCH' R&I with societal demands and values. The workshop concept has allowed for multi-stakeholder engagement and interchange of viewpoints from the consortium, industry, care providers, health professionals, policymaking and government, civil society, and patient organisations. Issues that were discussed and negotiated included identification and assessment of risks and benefits, of conflicting values and interests, potential barriers to use, hazard identification, ethical, legal, and social implications, professional needs. The briefing notes from the workshops had the purpose of informing the consortium and were followed by an internal, lessons-oriented de-briefing of the consortium members in order to facilitate meaningful and effective integration of the workshop results in the project work. The workshops discussed professional needs, ethical, legal, and regulatory aspects that needed to be taken into consideration in the innovation process, or in the use of the application as a product.

- The first workshop focussed on the needs, problems, requirements, and possible social and ethical issues that are foreseen to follow alongside a research project like COUCH.
- The second workshop focussed on how the core RRI issues are being tackled in the project.
- The third workshop addressed the question of responsible exploitation and the afterlife of the Council of Coaches application after the project comes to an end.

Alongside the stakeholder engagement process, the future audience for the application consisting of targeted (primary) end-user groups have been consulted and involved in the design of the technology and innovation processes in WP3 - WP6. After the delivery of the project's first functional prototype (M9) continuous evaluation and requirements updates have taken place, based on the information obtained. The user studies have delivered initial user requirements in order to provide valuable insights of end-users' needs, preferences and concerns in relation to usability, needed skills, security, data protection, ethical and social impacts etc. The focus of the evaluations has gradually shifted from acceptance (with low-fidelity prototypes, M9) to usability and user experience (with high fidelity prototypes, M15) and

more specific aspects of human-computer interaction in the final functional prototype (M21). For this goal, the end-user groups were treated as 'co-designers' among the older adult population. As our goal is to collect redesign input, we have primarily utilized qualitative data collection methods such as task-based interaction combined with thinking aloud, observations and interviews. All problems have been prioritized (critical, serious, or cosmetic) and translated into redesign documentation.

Practically, end-user groups (of 5-10 users) have been consulted in three countries (Denmark, the Netherlands, United Kingdom) to obtain user insights from different social, economic, and cultural settings.

## 4 Process and findings

### 4.1 Participatory innovation: An interweaved, collaborative process

The final overview of activities carried out in relation to the operationalization of the collaborative ambitions of the RRI Vision. By interweaving the processes of committing to a shared vision of responsibility, socio-technical integration and stakeholder and user engagement, letting inputs from either inform the others, we believe we have met our goals of ensuring that the research and innovation process in the project follows the EU principles of Responsible Research and Innovation, ensuring that the R&I processes in project contribute effectively to the needs of future users and the wider society, and ensuring that our R&I is aligned with societal values and ethical considerations and have a realistic chance of succeeding in the market.

**Table 4: Overview of RRI activities.**

Activity	Participants and purpose	Timing and place
1 <sup>st</sup> stakeholder workshop	Stakeholders, obtain input for the RRI Vision	Copenhagen January 2018 (M5)
RRI Vision workshop	Consortium, agree on the RRI Vision	Copenhagen January 2018 (M5)
1 <sup>st</sup> stiRRIng workshop	Consortium, reflective work on 4 main RRI issues	Valencia March 2018 (M7)
User study	Users, diary study in 3 countries featuring health information from the target audience, serves as basis for the technological development of the Functional Demonstrator. For elaborate information, see D2.3	Enschede, Dundee, Copenhagen (M8- M10)
2 <sup>nd</sup> stiRRIng workshop	Consortium, reflective work on secondary RRI issues	Enschede April 2018 (M8)
3 <sup>rd</sup> stiRRIng workshop	Consortium, reflective work on workflows	Dundee June 2018 (M10)
4 <sup>th</sup> stiRRIng workshop	Consortium, reflective work on 4 main RRI issues and desirable stakeholder inputs for stakeholder workshop 2	Enschede October 2018 (M14)
Workshop on “Innovation uptake in eHealth with patient-centeredness and gamification. Regulatory challenges and opportunities”	Stakeholders and medical experts. Brainstorm on the status of the regulatory and ethical scenario in the context of eHealth.	Brussels November 2018 (M15)
2 <sup>nd</sup> stakeholder workshop	Stakeholders, inputs on 4 main RRI issues	Brussels February 2019 (M18)



5 <sup>th</sup> stiRRIng workshop	Consortium, reflective work on outputs from stakeholder workshop 2 and responsible exploitation	Enschede March 2019 (M19)
3 <sup>rd</sup> stakeholder workshop	Stakeholders, inputs on responsible exploitation	Online event May 2020 (M33)

In addition to the RRI work conducted with stakeholders and users, the user evaluation process of the three Functional prototypes and the final Technical prototype have followed the schedule beneath. For elaborate information on these evaluations, see D2.4, D2.5, D2.6 and D7.7.

**Table 5: Overview of user evaluations.**

Council of Coaches Evaluation Cycles	
Cycle 1	
M9	Milestone 2: First Functional Prototype
M12	D2.4: Evaluation results of first functional prototype and updated requirements
Cycle 2	
M15	Milestone 3: Second Functional Prototype
M18	D2.5: Evaluation results of second functional prototype and updated requirements
Cycle 3	
M21	Milestone 4: Third Functional Prototype
M24	D2.6: Evaluation results of third functional prototype and updated requirements
Cycle 4	
M27	Milestone 5: Technical Prototype
M36	D7.7: Final Demonstration Results

## 4.2 The RRI Vision: A roadmap for the Council of Coaches responsibility work

In M5, the foundational event of the first process – committing to a vision of responsibility in the concrete project at hand – was carried out in the form of a physical workshop in Copenhagen attended by the partners of the consortium. We defined the object of this endeavour, our ‘RRI Vision’ as

*an agreement between the project partners about what responsibilities arise from the ambitions of the project, who needs to bear these responsibilities, and how the project is going to ensure that they do*

The workshop had the exact purpose of identifying the core RRI issues that would stay in the centre of the project’s attention as long as the project lasted, and this was successfully done in a semi-structured and co-creative process facilitated by WP2 which would later become the ‘RRI-team’.

The proceedings and results of this event has been extensively documented in D2.1, and the idea and format are described in chapter 2.2 and 3.2 of this report.

### 4.3 StiRRing the consortium: Internal RRI-workshops and a reflective endeavour

The socio-technical integration process carried out in the project was inspired by the American STIR initiative but adapted to a European research context and for a project made up of a consortium with partners spread out throughout Europe. Our model was based on a ‘flying squad’ concept, where the RRI team would travel out when the consortium was gathered for other activities (consortium meetings and – in most cases – technical integration hackathons, where the tech partners would meet for typically a week and build parts of the platform and the application) and conduct so-called RRI mini-workshops, lasting between 2-4 hours each, to tap in on the exchanges already taking place, insert reflection sessions on the RRI issues and contribute to making the focus on the issues an omnipresent dimension of the project work.

The format of these mini-workshops was a co-creative, dialogue based exchange, where the partners produced a considerable amount of text, as they were asked to write everything down – for the RRI teams expanding portfolio of material, but also in order to imprint the reflections by proxy as an embodied way to steer the focus towards the issues in multiple ways. The themes of the series of workshops was roughly decided at the beginning of the process, but only in a very open-ended manner that would leave space to tailor the specifics to the actual needs and debates in the consortium at the time of the mini-workshop. And overall, a very concrete integration of process and knowledge was a core guiding principle for the workshops, so that the themes and working questions would take their point of departure in perspectives, questions and advice from stakeholders and users (obtained in the stakeholder workshops and user studies and evaluations) just as the themes we discussed with stakeholders (especially) and users were developed directly out of concerns and inquiries raised by partners. Also we made sure to bring material from requested debates with stakeholders back to the consortium as yet a new, redesigned topic for debate and reflection. By minutely designing our process on these aims and principles – one eye on the project plan, the other on ongoing debates and challenges in the project – and tailoring our concrete interventions guided by empirical flows as well as scripted protocols, we believed we succeeded big time in keeping the project’s focus continually on the RRI-issues and creating deep reflection and ownership of the responsibilities. Just as we actually developed a genuine method for handling RRI-issues in health tech projects on a scale comparable to the Council of Coaches.

The list of mini-workshops conducted is listed above. The minute details of the proceeding of the mini-workshops and the empirical material resulting from this work is the topic of D2.7.

### 4.4 Bringing the outside in: Stakeholder perspectives on RRI issues

In the following the proceedings and conclusions from the three stakeholder workshops are presented. Prior to the workshops, interviews with key stakeholders in three different countries were conducted in order to take different cultural and social settings into account in the design of the workshop themes and infrastructure.

The themes and composition of the stakeholder groups was all the way through the project a result of close consideration of the ongoing discussions in the consortium at a given point in time and stage of technical development and innovation – we were very careful to design the stakeholder activities in accordance with the actual needs in order to secure prolific dialogue and exchange between the inside and the outside of the project – to ask stakeholders the same questions the consortium was struggling with and benefit from other perspectives, and make sure to bring the knowledge back into the consortium and stir discussion and creativity. Also, the results and perspectives from the workshops were brought directly into the ongoing work with the Functional Demonstrator prototypes as yet another way to ensure a close fit with user needs and societal expectations in our work.

#### 4.4.1 First stakeholder workshop: RRI Vision Workshop

The first stakeholder workshop was carried out in M5, in connection with creating the RRI Vision in the consortium, where foundational perspectives related to the RRI Vision were included in the introductory work.

For this initial workshop, the main purpose was to obtain advice and attitudes toward the technology from different stakeholders. The consortium works with the stakeholder understanding, of it being all the persons or organizations that have a task or role in relation with, or are affected by, the eHealth intervention (Mitchell, Agle, & Wood, 1997). Initially a broad stakeholder group exercise was carried out, which identified relevant stakeholder groups by mapping and brainstorming the fields of virtual and traditional coaching, eHealth and mHealth. The chart was expected to would give us an idea of the most relevant stakeholders to bring in for the later workshops and interviews.

To gather a broader stakeholder perspective, different stakeholders were invited to the first stakeholder workshop (in Copenhagen). The stakeholder workshop as a methodical approach is drawing on the ideas of a co-design approach where designers, developers and other people not trained in design are working together in the design development process (Sanders & Stappers, 2008). Only three stakeholders with different backgrounds attended the actual workshop, but to cover the spectrum of stakeholders identified in the initial stakeholder mapping, in depth-interviews were conducted with some of the identified people who were not able to make it to the workshop, featuring a psychologist (with an expertise in health coaching), a policy maker with technological expertise, and a first-mover within the field of mHealth.

A detailed account of the proceedings and results is presented in D2.2. For reference, the interim observations and conclusions are repeated here:

#### **Interim observations and conclusions from the workshop**

The stakeholder involvement provided a long list of responsibility insights from experts within the broad field that the Council of Coaches covers. There are different RRI-issues that are very explicit and should be taken into account in the responsible development of Council of Coaches. These explicit issues are listed below:

- The Council of Coaches can identify the level of motivation that the patient is at and adapt the coaching to that level.
- The Council of Coaches should not make the patient feel bad about him/her, as Council of Coaches then isn't advising into the right motivational level. Use empathy and open reflections.
- The Council of Coaches shall make the use of data transparent to the patient. The patient should have a clear idea of everything that can be done with his/her data.
- Not everybody might be able to use Council of Coaches which can lead to certain social groups being forgotten in the healthcare system or marginalized. Be very aware of which people can use Council of Coaches and which people can't!
- Be aware of the patient's needs! Don't try to solve a big problem through Council of Coaches when Council of Coaches isn't necessary.
- The app has both the potential of becoming an educating tool and a tool that makes people uncritical. Make sure it comes out as an educational health tool in the end!

The stakeholders are to some degree unsure of how the implementation strategies should look like, but there is a general agreement in the argument, that people won't use the technology if the implementation is strongly pull-based and to no degree recommended or pushed out by experts. That being said, it should make sense for personnel to use it and to recommend it.

Whether the coaching strategy should be persuasive or reflective depends on the patients need. The coaching strategy should therefore be flexible both due to the course and development of the patient's disease and due to the level of motivation.

#### **4.4.2 Second stakeholder workshop: Responsible development in health tech**

The second stakeholder workshop was structured around three primary RRI issues: privacy and informed consent; multiple knowledge sources; and trust. The aim of the workshop was to gather stakeholder opinions on the relevance and effectiveness of our ongoing strategies for handling these issues as well as advice on how to improve them. In the context of the workshop we hoped to gather concrete advice on how to proceed in the second half of the project, which examples to learn from, and how to get around any blind spots apparent to the stakeholders.

## Context

The stakeholders gave their input in response to a set of questions formulated by COUCH participants at a previous RRI mini-workshop held in conjunction with a technical integration week (in Twente, October 2018). As far as possible, the participants at the workshop represented the categories of stakeholders requested by the consortium members. By giving the consortium members involved in the technical integration the opportunity to reach out to stakeholders in this way, our hope is that the input has been directly relevant to the choices to be made in the final phases of the project.

## Method

The Brussels workshop made use of a standard groupwork setup. Participants had received briefing material in advance, and some of the participants had been interviewed over the phone to help us strike the right note in terms of their advance understanding of the subject. The briefing material is included as an appendix to this debriefing.

After receiving a common introduction to the COUCH project and the RRI issues in it, the participants were divided into four groups. The four groups engaged in discussion of the three RRI issues in three separate sessions and reported back to the plenary at the end of each session followed by a brief plenary discussion. At the end of the day, everyone gathered on the balcony for drinks. Not relevant to the outcomes, but very enjoyable!

The discussion at the workshop addressed the key aspects of the current strategies for handling the RRI issues. Consortium members had requested feedback on specific questions formulated by the participants at the previous RRI mini-workshop. To stimulate discussions that would help to elicit such feedback, we presented the participants with the key elements of COUCH's current strategy on each of the RRI issues. We then posed three questions to them, namely: How well are we doing? Do you know any examples of groups doing better? And what would you recommend that we change to improve our approach. From the ensuing debates, we can extract the following responses to the original questions.

### *4.4.2.1 Outcomes of session 1: Privacy and informed consent*

#### **How to handle partial consent?**

This question is directly related to the 'building blocks' approach to consent adopted early in the project. With this approach users will be able to give consent to data gathering selectively. The broader consent is given, the more of the system's capabilities will be available to the user. But can the system give reliable advice based on a partial picture? Also, how do we handle giving access to the data to some third parties (e.g. general practitioners) and not others?

Responses from the stakeholders start from the basic premise that the user's control over data is to be taken seriously and not to be overridden or circumvented. Even though there are many good reasons to want to work with all the available data, you cannot build a platform that users will trust without sticking to the principles of user ownership and control over data. In that respect the building blocks approach is a good idea and something that other systems have also implemented. The user who does not opt-in on certain aspects of the system's data gathering and processing capabilities will not experience the service provided as lacking, but as addressing precisely those aspects that are interesting to that user. Could the systems provide 'better' and more nuanced advice with access to more data? Certainly, but not to this user, whose preferences should serve as the guiding light for the system. In any case, no version of the Council of Coaches will be able to provide 'complete' or fool-proof advice. So, the limitations will be there in any case.

That said, there are solutions out there that seek to navigate between protecting the privacy of individual users while at the same time creating value from data. One stakeholder gave the advice to look closer at the MIT OPAL (Open Algorithms for Better Decisions) approach. This approach is encapsulated in the phrase "send the code to the data". According to the stakeholder in question, in OPAL the raw data is not stored in one place but is analyzed early on and thereby anonymized. Only then is the result stored, while the core data is discarded, thereby eliminating the concern for privacy. The OPAL platform includes both a technical and governance component (<https://www.opalproject.org/a-closer-look>).

Turning to the core question of how to handle partial consent and 3<sup>rd</sup> party access, two cases were mentioned which may provide inspiration.

One case is the Patients Know Best, a UK-based provider of a shared, digital patient record that you, the patient, have full control over. With this record patients can choose to share non-clinical data with all the actors involved in their journey through the healthcare system. The providers' privacy policy shares some similarities with the 'building blocks' approach to informed consent in that patients can switch sharing with particular 3<sup>rd</sup> parties on and off as they go. Inspiration might be drawn from the full gamut of legal work around the service (<https://help.patientsknowbest.com/Legal.html>). But a stakeholder employed by the provider – speaking here in a personal capacity – gave the warning that it is ultimately not possible to create a privacy policy *a priori*. The devil is in the detail, and the details derive from two decisions that COUCH has not yet fully taken: Which is the territory in which the privacy policy is going to have validity? And who exactly are the users and 3<sup>rd</sup> parties involved. This boils down to the question: Who is the exact target group of COUCH?

Another case, which one stakeholder held out as paradigmatic, is Patients Like Me. This “not just for profit” US-based organization provides a platform on which those who suffer from hard-to-treat diseases can share experiences and data about their symptoms, effects of treatments, and more. The organization has been highly successful in establishing a vibrant community with 600.000 users and counting and garnering tens of millions of dollars of investments. What is interesting about the organization in this context is that its basic business model is based on exactly what we in COUCH tend to back away from, namely selling user data for use by 3<sup>rd</sup> parties. But in contrast to other more or less shady business models based on reselling data with dubious consent, Patients Like Me is out in the open with their strategy. They supply medical researchers, pharma companies, insurance companies, nonprofits, and government agencies with anonymized variants of their user's data precisely as a way of helping these third parties help their users. This seems in fact to be part of the appeal to users. A discussion paper (Grajales et al. 2014) – which is written by a group of authors with several members from Patients Like Me – finds based on two separate surveys that more than 90% of American users are willing to share their health data if properly anonymized to help patients in a similar situation. Between 77 – 90% were willing to share data even if the third party was a commercial drug company. So, it is possible to accompany a strict privacy policy with a “philosophy of openness”; an approach that might inform the Council of Coaches approach to privacy vs. 3<sup>rd</sup> party access. To be sure, far from all participants see such a business model as unproblematic. Some consider reselling data unethical, another even talked about ‘prostitution’ of data. It is a minefield, but worth considering.

### **How do we provide meaningful information on data processing?**

This question has to do with the vehicles used for gathering consent. It is likely that we will have users who are not able to read, let alone understand the processing of personal data that goes on inside the Council of Coaches. How can we communicate the various options for consent to data gathering and what these options imply? Could we, for instance, communicate options for consent and additional functionality using the coaches themselves? If so, what would the dialogue look like?

The stakeholders raised several concerns about this approach. Firstly, it is important to take seriously that there may be users – children or impaired adults – who are not able to give meaningful consent under any form. Secondly, it is important that the ‘full’ legal information be made available alongside any ‘easy to read’ version. To be sure, the GDPR explicates that the ‘full’ version should also be ‘easy’ to read; but obviously there will be a distinction between the long and the short version. If the long version is not made available, COUCH would have failed to provide the information needed for consent to be valid.

The stakeholders liked the overall idea of presenting information in an accessible way. One group discussed the idea of having a ‘lawyer’ coach that would be able to explain both the long and the full version of it. However, even here it would probably be important to ensure that the ‘full’ version is available in a written form that is outside of the interactions with the coaches. If not, COUCH might be accused of ‘gamifying’ the consent situation and thereby biasing the individuals.



In any case, since the level of functionality available to users is tied to the level of consent given by users, it is especially important not to influence users by skewering their understanding of what consent implies, e.g. by downplaying risks and overemphasizing benefits.

#### **Who is legally liable and for what?**

This question is a natural offshoot of the attempt to reach GDPR compliance. Even if we are compliant with data protection legislation, who would be legally responsible in case the system provides scientifically outdated or outright wrong health advice? Can we somehow ensure that the user understands and accepts that the system is fallible with all that this entails of potentially wrong advice, system crashes, etc.?

Participants stressed that legal liability is a real issue and potentially a showstopper for uptake of COUCH, but also explained that we cannot settle legal liability issues without being more specific about the applications we are trying to develop. The privacy discussion along with broader liability discussions should be framed in an exploitation context. Some of the questions the project should be able to answer are: Who is going to own COUCH in 10 years? Which territories is it going to be deployed in? Aimed at which users? With which 3<sup>rd</sup> parties onboard? Providing answers to these questions is needed before any kind of meaningful legal analysis can be made, not to mention deciding on a strategy to handle them. At the same time, without such an analysis, there will be no exploitation – at least not by outside parties – because a company taking up the technology, or an investor seeking to establish such a company, would have too many unanswered questions to be able to assess the risks involved.

Relevant legal frameworks go beyond GDPR. Other relevant frameworks include the European medical devices directive and good medical practice standards. One participant recommended outright: talk to a lawyer. These issues are not going to be easy to map or settle, and they are going to be crucial for any attempt at going to market. Simple measures – such as defining the COUCH product as ‘not a medical device’ or providing a disclaimer saying that ‘COUCH assumes no responsibility for what you do with this information’ – is bound to be legally problematic at least in some cases. So, between the COUCH development process and the implementation of COUCH in any real context there is a legal hurdle to cross. Another participant stressed the need to decide on a concrete user group and market; without such a decision, the issue of liability will stay in flux and the technology will remain at an early stage of development.

#### *4.4.2.2 Outcomes of session 2: Multiple knowledge sources*

##### **How to ensure that correct advice is given despite conflicts between coaches?**

One group leaned in the direction that conflicts between knowledge sources should always be resolved by the user deciding which way to go. This could extend to all advice given: an accept/ignore button could be an integral part of any advice-giving by the system. This would both help to circumvent the problem of settling conflicts in the underlying software and it would help to strengthen the AI by teaching it which advice is accepted and which is not.

This view was supplemented by another group having the view that the system should back away from ‘advice’ (mobilizing knowledge) and lean towards ‘coaching’ (asking open-ended questions, rephrasing, listening). A ‘peer’ coach might perform this function.

Another third leaned towards hiding conflicts away from the user except where there is real risk associated with the choice between two options. Here, the conflict should be resolved either by the user or by the GP. An important observation here was that some users might prefer to be exposed to the conflict while others would want the system to settle the conflict for them. Perhaps it would be possible to make assumptions about this based on background (e.g. European North vs South) or sentiment mining (testing how users react to conflicts). It could also simply be a setup choice.

A fourth group stressed that if there are conflicts there should be full transparency for the user about the assumptions and the knowledge base built into the system. Only with such transparency will the user be in position to determine what to do about the conflict.

It would in any case be important to clarify the role of the medical coach and how it is different from that of a clinician. Whereas a clinician will diagnose you, medical advice may be viewed as providing broader insights into medical knowledge that is relevant to a specific symptom or some other concern. If there is going to be a clinician among the coaches, the company operating the system would assume extensive liability and there would be a whole layer of certifications along with checks and balances that would have to be implemented. Even the term medical 'advice' may still be too strong to avoid a great deal of liability and obligation – Patients Like Me, for instance, explicitly states that the site does not provide medical advice. (This may have to do with the wording in US law). If there is 'only' a medical coach, that coach would be able to add value by providing medical coaching – e.g. guidance through knowledge sources; follow-up on medical treatments set in motion by the GP etc. - without delving into diagnosis or treatment.

To the degree that the system does give advice, it is important to understand that the data for each user might then be classified as a medical record and must conform to the rules and regulation for such records.

Finally, it is important to decide when to call in professional help. One example that strikes a balance between AI-based advice and professional help is Babylon Health (<https://www.babylonhealth.com/>). This UK-based service combines a continuously improving AI engine that helps users to navigate symptoms and potential treatments with a network of actual GPs and other clinicians that stand ready to make professional assessments and give clinical advice. This combination of services circumvents the problem that no AI-based product could – at least in the foreseeable future – actually take over the diagnostic role and responsibilities of a medical professional.

#### **How to make sure the information-base is up to date?**

One possible answer seems to be: Through organized effort. All the examples mentioned by practitioners that provide medical advice or knowledge to users is supported by extensive work by staff and in some cases users to update and refine the database of available information. If the Council of Coaches is not going to have its own back-office staff working on the database in this way, integration with existing organization that do this work would seem to be the only workaround.

To be sure, no-one presented a solution for how to stay fully up to date with all medical knowledge. But given the many suggestions to back away from an actual clinical role, perhaps that is not the right goal to have.

#### **How to stay in the 'safe-zone' of advice while still producing value for the user?**

Some practitioners made a point of emphasizing non-medical coaches and the value they might produce. An actual coach would – as stated above – not give advice but rather pose open-ended questions, reflect the user's answers, and drill into the underlying assumptions. Furthermore, in a real-world health-oriented coaching setting, it is likely that the user would be paired up with someone with greater experience of living with the symptoms in questions, i.e. a 'peer' coach. The role of the peer would be to provide an anchor point for the user – someone to identify with – as well as the consolation that someone who was previously in the situation the user is in now has been able to move forward by applying some very general advice.

Some of the participants seemed to think that these non-medical and non-advice-giving coaches could in fact provide the most value given that medical/clinical advice and treatment might already be well covered by the actual healthcare system around the user. It would thus be the supplementary role that the coaches could play that would provide the value.

#### *4.4.2.3 Outcomes of session 3: Trust; not too little, not too much*

#### **Where is the balance point between trust-building and helping vs manipulation and overreliance?**

With regard to trust-building there were different takes on what the fundamental conditions for trust are. One group emphasized transparency; what does the system do, what can the user expect, what does the system provider expect of the user, what kinds of data and data crunching does the system rely on, etc. Another group emphasized the importance of the institutional and organizational underpinnings of the system. There is no doubt a technical and design dimension to trust-building, but the real linchpin

of building trust has to do with is going to be governance structures, certification on various dimensions (from cyber security to coaching ethics), contractual relations with users, health care professionals, and 3<sup>rd</sup> parties. An obvious example would be if the system is recommended by the GP and embedded in treatment procedures. A third group discussed learning-as-we-go as a means of building trust; i.e. if the user is able to report errors or bad experiences with the system and these are corrected consistently, this would build trust over time. There was broad recognition that 'blind' trust is to be avoided while 'evidence-based' trust is the real goal.

An interesting part of the discussion of trust-building were ideas of 'reverse-engineering' trust-building by going from obvious ways in which trust would be broken to ways in which to avoid that. One obvious example would be if the coaches contradict the GP, and thus trust-building would seem to imply some degree of coordination with the GP. Another way of breaking trust would be if the system is unable to respond to the user's situation; e.g. taking breaks from the Council sessions during vacations; make accommodations for the extra food that everybody eats around Christmas; no walks if you broke your foot; and so on. A third way of breaking trust would be if the system continues to push the user towards a previously set goal long after it is clear to everyone involved that the user will not reach that goal. In that situation it would be necessary for the trust-relationship that the coaches state candidly that the goal seems to be out of reach and maybe the user should reset his or her goals. Finally, there is a clear link between the issue of privacy breaches and the maintenance of trust, which was already discussed above. Overall, this strategy for probing means of trust-building through reverse engineering could be taken up in the group at an appropriate time.

Regarding the risk of creating overreliance there was a bit of discussion of the underlying premise. One group dismissed the worry, seeing the reference to overreliance discussions in robotic care as a stretch. Their argument was that the social dependence created by e.g. a robotic 'care' seal would not likely occur in relation to on-screen entities. However, at another point in the discussion the theme of overreliance came up again, this time with reference to the findings from the end user studies in 2.3. You may remember that in the treatment of chronic pain there is a point where the patient is left alone in order to force a shift to self-management. Similarly, with human coaches it is part of their ethical code to stop a coaching relationship when a coached person is deemed fully able to implement the goals of the coaching on their own. This point got more traction from the participants as a relevant issue to manage. From this angle, however, the question of overreliance turns immediately into a question of goal setting. What are the goals of the coaching in terms of changing life strategies or health management strategies, and when (and how) do we judge that the user is 'there'? While relevant, the question of overreliance cannot be managed without a more concrete decision on what kind of goals the user is going to be able to set. Likewise, if ultimately we decide not to include goal setting as a central feature of the system, the question of overreliance might become moot as there would be no way benchmark to separate a period of necessary reliance (while learning new life skills) from a period of overreliance (relying on the system for guidance even though the user should already be able to maintain a new balance in their life). Finally, despite this relevance it would still be possible to argue that 'over'-reliance may be a misrepresentation of the relationship between the user and the system; even if the user becomes permanently reliant on the system. Simply because the system is an always-available resource that the user has full control over. Especially if use of the system would be free – or the cost negligible – to the user, the risk of overreliance might be deemed irrelevant or at least no riskier than our reliance on other apps that let us deposit our brains in our phones (map apps, contact books, etc.).

As regards solutions to avoid overreliance, some different ideas were discussed. One strategy was based around the idea of emphasizing the unreality of the coaches; by having strange things occur (e.g. an arm falls off, a coach levitates) or by having a less-than-real type of skin (e.g. sticking with the blob-men). Another strategy emphasized the limits to the competence of the coaches through the dialogue (e.g. "I really don't know", or – "How would I know, I'm just a robot, you know" or something along those lines).

### **What is the proper relationship between the system and health professionals involved in the user's care?**

There was no clear resolution of this issue at the workshop. The relationship between the system and health care professionals is really a key issue, and much discussion touched upon the issue. Some of



the ideas that came up – most of which are well-known to the COUCH group – were: having a warning function going directly to a healthcare professional in case the system detects suicidal tendencies or symptoms of an underlying medical condition; integrating the Council of Coaches in a healthcare plan designed by the GP; and others. But there was broad agreement that this issue cannot be settled in the abstract; it depends on the specific context. Not only is important to decide which patient groups the system is designed for, it is also important to decide which parts of their care is supported, which specific actors to involve (e.g. the GP), and which countries to go into.

#### **Who is liable for medical malpractice if the system is embedded in ordinary healthcare?**

The same point as above: no clear answer, depends on the context. But the important message is: We do not get a pass simply by deciding to say that the Council is not a medical device. If we are using it like a medical device, then it will be covered by the regulations. In any case, standards and regulations for good medical practice will most likely apply. The advice again is: Decide on the application area; then go see a lawyer.

#### *4.4.2.4 Emergent issues: RRI can only be realized in a well-defined exploitation plan*

The main issue that emerged unplanned during the discussions, was the centrality of the link between the RRI issues and the exploitation plan. We were already well aware of this, and it was also the theme of the workshop held in the autumn of 2018 – here, a few of the participants stressed very strongly the need to decide on specific application areas and start planning for (commercial) exploitation. This was not a message coming from everywhere, but specifically it came from some of the commercial actors in the room. Their suggestion seemed to be that the project should: decide on an application area; partner up with a commercial actor active in that area; carry out specific use case studies to decide on design and implementation; supplement the final prototyping stages with specific legal and contractual efforts to prepare commercialization after the end of the project. This input has already been taken up in the innovation management group, but it has also informed our further discussions about how to implement the RRI strategy in the final stages of the project.

#### **4.4.3 Third stakeholder workshop: Responsible exploitation**

The theme of the third stakeholder workshop ‘responsible exploitation’ had the purpose of evaluating and further developing guidelines towards a practical approach to responsible prototyping suitable for the Council of Coaches and similar projects. The participating stakeholder groups were identified through stakeholder mapping and brainstorming in the fields of virtual and traditional coaching, eHealth, mHealth, ICT, health authorities/governance, health professionals/organizations, health tech, industry and the patient organisations related to the focus of Council of Coaches.

The workshop was planned to be launched in March 2020 in the shape of a physical event in Brussels. However, due to the incident of COVID-19, the event was first postponed and after some time redesigned into an online format (using the platform Zoom). This makeover gave us the opportunity to expand our geographical coverage regarding participants as well as the scope of themes. Therefore, a second round of identifying stakeholder groups took place, now also within the fields of sustainability, disaster management, and climate. These stakeholder-groups included climate innovators, the energy sector, sustainability innovators, climate authorities/governance, sustainability professionals/organizations/think tanks, sustainability tech/innovators, industry, and research.

#### **Workshop format**

The broad criteria and related stakeholder-groups were designed to complement a desire for high diversity in stakeholder perspectives. Unlike our previous workshops, this concluding workshop did not require knowledge particular to the field of eHealth but expanded its scope to a more general use of virtual coaches. All input from the participants was directed towards evaluating and further developing guidelines for a practical approach to responsible prototyping suitable for the Council of Coaches and similar projects. The workshop format was inspired by the methodological approach of co-creative design practices staged through stakeholder scenarios. With this method the participants (stakeholders, planners, and consortium members) were all contributing to the process of developing the recommendations. The scenarios were developed in small groups, discussed in plenum, and finally condensed.

### Workshop structure

Due to its online format the workshop was divided into three separate sessions, estimated to last approximately 1½ hour- 2 hours. In our experience, longer stretches of time spent in online meetings deteriorate the participants' attention and attitude. The two first sessions were executed on two consecutive days, and the third session a week later.

- Session 1: Multi knowledge coaching - Date: Monday May 11
- Session 2: Trust and good scepticisms - Date: Tuesday May 12
- Session 3: Co-drafting of recommendations - Date: Wednesday May 20

### Session 1 and session 2

The two first sessions were open to all participants, while the third required participation in at least one of the two first sessions. The participants were introduced to the project specificities in the following way:

- General purpose of the project
- Introduction to the COUCH project,
- Introduction to the field of Responsible Research and Innovation, and
- Introduction to the current session's RRI issue (Multi knowledge coaching and Trust and good scepticism, respectively).

In each session, three rounds of discussions were carried out. Within each round the participants were divided into pairs of 2 or 3 (using online breakout-groups). Here the assignment was to deliberate on the session's RRI-issue. Between each of the rounds the results were discussed briefly in plenum which gave everybody the opportunity to dig deeper into the issues.

The **first** round of deliberation gave the participants the opportunity to project the session topic from the perspective of the stakeholder and the group, discipline, and institution they represented.

The **second** round used 'scenario workshop' methods and asked the participants to imagine future scenarios for the session topics. This task was divided into two sub-questions:

- 1) What is the dream scenario(s)?
- 2) What is worst scenario(s)?

In the **third** round these scenarios were then brought to a vote based on relatability, to explore which perspectives were considered most concerning across the stakeholder groups. The scenarios with the most votes were then presented in greater detail and discussed by the participants. The workshop sessions were finalized by a general discussion between all participants.

### Session 3

In the third session, with the theme 'Co-drafting recommendations', the focus was more specific. The participants were asked to address the scenarios presented in the previous two workshop sessions and produce reviewed strategies 'towards them' or to 'avoid them'. The scenarios had been condensed and similar scenarios had been assembled. Through sessions of 5-10 minutes the participants wrote their strategies in a shared document and then discussed them.

This session produced two different kinds of input: (1) defining the dream scenario and how to get there, and (2) defining the worst-case scenarios and how to avoid them. The inputs were written into the shared document by the participants and later edited. All the workshops were recorded.

#### 4.4.3.1 Outcomes of the workshop

The finalized scenarios and strategies from the workshop are presented below with the corresponding recommendations elaborated in session 3. The results have been edited for clarity but otherwise remain as described by the participants.

#### Scenarios and strategies: Multi knowledge coaching

This scenario explores the implications of multi coaching in practice, and how to ensure that the multifaceted and potentially conflicting advice given serves to heighten the user's quality of life rather than creating confusion and inconvenience. The participants went deep into the worst and best thinkable unfolding of the scenario:

Table 6: Multi knowledge coaching, worst-case scenarios.

From Workshop	Reviewed: Strategies to avoid it
<p><b>1. Biased recommendations and corruption: If the providers of the Council of Coaches receive money from companies willing to favour the medical recommendations (for instance a pharma company trying to recommend the use of their drugs)</b></p>	<ul style="list-style-type: none"> <li>▪ 2 approaches: either not accept money from commercial actors OR accept contributions but bias needs to be highlighted</li> <li>▪ Avoid payments coming from any of these actors. Recommendations should be coming only from independent professionals.</li> <li>▪ One way to avoid it would be to open-source the “recommendation” algorithms built-in (that way, the community can verify that there is no bias).</li> <li>▪ Side note: how does this work with GPs? Are they allowed to push for using certain drugs because they receive money from a pharmaceutical company?</li> </ul>
<p><b>2. Freedom of choice and liability: non-use or ignoring of advice leads to increased health insurance premiums.</b></p>	<ul style="list-style-type: none"> <li>▪ Not so much an issue in EU at the moment because regulatory safeguards but entity that commercialises council of coaches could also allow use if users are shielded from negative consequences as described</li> <li>▪ Increase in health insurance premiums cannot be calculated using only these actions. This cannot be a central calculation model.</li> </ul>
<p><b>3. Liability: Who is responsible if a user receives a result which has significant negative consequences for the user’s health without having a safety net from the healthcare system. Upon whom lies the responsibility?</b></p>	<ul style="list-style-type: none"> <li>▪ Responsibility is not clear as this is not regulated yet. It will require clear regulations. In this case, the final responsibility is for the patient but that makes no real sense as the person is not a specialist and is using it because he/she needs it.</li> <li>▪ Well-being recommendations should not elicit liability; healthcare recommendations to be checked by individual’s GP before they are given</li> <li>▪ I was looking for the type of problems typical for the technology. Most issues also hold for human coaches. In artificial systems, the humans involved are hidden for the user. Responsibility is a hard problem.</li> </ul>
<p><b>4. Unintended usage: If multiple users are interacting with the Council of Coaches with the same account and interpretation ends up with</b></p>	<ul style="list-style-type: none"> <li>▪ The application should make clear and frequently remind, that it should not be used by multiple users under the same account.</li> </ul>

<p><b>more conflicting or potentially dangerous results.</b></p>	<ul style="list-style-type: none"> <li>▪ The application may facilitate the use by different people but with different profiles. A warning on this respect should appear every single time the user enters the app.</li> <li>▪ Include recognition through speech (e.g. system asks “Good morning. Who am I talking to today?” and user states his name so that the system knows who it is dealing with?</li> <li>▪ Do users consider the information they share with a coach as private in the sense that it should not be shared with another coach? How can they be sure about this? Or do they know all information is shared by all coaches?</li> </ul>
<p><b>5. Hacking back the system: The elderly participates in these programs because their children want them to. They gradually learn what the system expects and hack it back: pay local kids to walk their fitness band and put the healthy products on smart spoons, while themselves eating less healthy foods.</b></p>	<ul style="list-style-type: none"> <li>▪ Sad for the system but a person should have the right NOT to participate in the system if they do not want to (autonomy)</li> <li>▪ This is part of human nature. It is a matter of adherence. There is no real way to control this. People should make responsible use of the application as it is dealing with his/her own health.</li> <li>▪ Not really avoidable. And if there were to be systems in place to detect the improper generation of sensor data - these should be implemented by the sensor data providers (Council of Coaches is designed to work with 3rd party sensors).</li> </ul>
<p><b>6. Worsen conditions:</b></p> <ul style="list-style-type: none"> <li>▪ <b>Worsen conditions that were hidden, not well declared, or underestimated by the final user.</b></li> <li>▪ <b>Your health gets worse while using the platform</b></li> <li>▪ <b>And the health care system does not want to take you back</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ The app may periodically check the overall status. A warning should be presented to the user: “In the case, something changes dramatically, let your medical professional know”.</li> <li>▪ This relates to the system having to instill a level of trust, but not too much: users should always think for themselves in “applying” the advice given, and when in doubt should be referred to standard care services.</li> <li>▪ The system could also ask periodically “X, how are you feeling today” and if scores get worse, recommend seeing a General Practitioner</li> </ul>
<p><b>7. Security:</b></p>	<ul style="list-style-type: none"> <li>▪ This aspect is key for an application like this one. Security of provide information, data, and the use of it should be preserved. However, there is always a part of the responsibility that should be ensured by the final user.</li> <li>▪ Security (from a technical point of view, i.e. making sure data stays safe) is extremely</li> </ul>

	important, but there is nothing specifically related to Council of Coaches that makes this issue any different.
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Table 7: Multi knowledge coaching, dream scenarios.

From Workshop	Reviewed: Strategies to reach it
1. <b>Positive feedback and reinforcement: Strengthen positive behaviour, developing the coaching methods to such a degree that people cannot resist it.</b>	<ul style="list-style-type: none"> <li>▪ A potential strategy is to really involve people with different needs. Not only concrete pro-active groups.</li> <li>▪ There is a very large group of researchers working on trying to achieve this :)</li> <li>▪ (Further?) involve behavioural psychologists?</li> </ul>
2. <b>Heighten the quality of life: The technology can help to engage in meaningful relations and give peace of mind to troubled people.</b>	<ul style="list-style-type: none"> <li>▪ Make sure the participants are not under any type of pressure. Freedom of choice is a must to reach this goal.</li> <li>▪ Include mindfulness approaches.</li> </ul>
3. <b>Multiple applications: A dream scenario would be if one would be able to use the Council of Coaches approach for managing other conditions that are also serious and will condition the future of young adults and adults.</b> <ul style="list-style-type: none"> <li>▪ The application can move into other fields than e-health</li> <li>▪ Enhanced communication between the Council of Coaches of different users for social engagement.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Many of the technology components should be “abstracted”, so that they can be readily reused in other applications. As more developers build “coaches” within the same technology framework, this “interoperability” may become available.</li> </ul>
4. <b>Personalisation: The application develops to become more and more personalised and adaptable. It learns from the user and can promote good advice specifically relevant for the users.</b>	<ul style="list-style-type: none"> <li>▪ Imagine a completely automated learning system that adapts to the individual user. Is that still a useful system? How do we control it? How do we measure its performance?</li> <li>▪ Using the combination of other data sources including the medical ones.</li> <li>▪ The system should (anonymously) log a large amount of information regarding the advice given and the (measured) reactions of the users so that the organisation behind Council of Coaches will have the knowledge on which strategies work for which users.</li> </ul>
5. <b>Process or outcome: If the council of coaches could be oriented to focusing on the process, not the achievement. The coach emphasizes</b>	<ul style="list-style-type: none"> <li>▪ The process as such for many people is a success. This aspect will empower many users to re-direct some of their habits.</li> </ul>

<b>the positive aspects of behaviour and reorients from the number achievement to the process.</b>	<ul style="list-style-type: none"> <li>I think this is a promising “design philosophy”.</li> </ul>
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### Scenarios and strategies: Trust and good scepticism

This issue considers the implications of handling trust-building in a reflexive manner, to support a balanced relationship between the Council and its users. A reasonable balance between trust and independence assist the future users in getting the most out of Council of Coaches without experiencing negative consequences of misinformation or overreliance in the application.

**Table 8: Trust and good scepticism, worst-case scenarios.**

From Workshop	Reviewed: Strategies to avoid it
<b>1. Data-Breach: sensitive information is leaking from the system.</b>	<ul style="list-style-type: none"> <li>Avoid storing sensitive information in the first place</li> <li>Strong IT security mechanisms. If possible, no storing of sensitive information.</li> </ul>
<b>2. Biased Information: Hidden Influences in a system that is blindly trusted (sponsored advice).</b>	<ul style="list-style-type: none"> <li>Similar to the worst scenario under multi-knowledge coaching.</li> </ul>
<b>3. Replace real people: The virtual Council of Coaches becomes a cheap replacement of human coaches and experts. Removing structural incentive to keep a ‘healthy’ health system operational.</b>	<ul style="list-style-type: none"> <li>This may happen but the “human contact” is a must normally in healthcare. There are many applications in the market that claim to be able to follow conditions but replacing a doctor or a coach is much more than that. Also, professionals may use it as support tool (as part of their own offering to their customers).</li> <li>The way to overcome this is to make policy makers aware of the possibilities and the impossibilities of these technical systems.</li> <li>The need for systems like Council of Coaches arises from the lack of availability of “human” healthcare professionals, especially in an ageing population. It will take a long time before the “roles are reversed”.</li> <li>Link with real people: e.g. recommend linking up with General Practitioner if worsening condition is detected or recommend to call family members to increase social interaction.</li> </ul>
<b>4. Invasive technology: The Council of Coaches are not trusted and feel invasive for the user. Both the content and process of the application is not trusted out of fear of being taken</b>	<ul style="list-style-type: none"> <li>Freedom to choose. Nobody should be using the application under any type of external pressure.</li> <li>The “organisation” that “sells” Council of Coaches should be trustworthy. Or, the</li> </ul>



<p><b>advantage of, as well as having one's data sold to third parties.</b></p>	<p>"sales channel" should be trusted by the user.</p> <ul style="list-style-type: none"> <li>▪ Users should be protected by law against invasion.</li> </ul>
<p><b>5. Blind trust: The uncritical and unreflective patient</b></p>	<ul style="list-style-type: none"> <li>▪ It may be possible to detect (by the manner in which people respond in the conversations with the coaches), how "critical and reflective" the user is. If not critical and reflective at all, the coaches could choose to never give any direct advice at all, instead just asking questions: "what do you think is healthier for you?".</li> <li>▪ Engage the user in discussions where they are asked to argue a different position e.g. system says "I recommend that you eat no more chocolate to lose weight, but you could also do some exercise. Convince me that you can lose weight while eating chocolate".</li> </ul>

Table 9: Trust and good scepticism, dream scenarios

From Workshop	Reviewed: Strategies to reach it
<p><b>1. Feeling empowered: Users have the feeling of "agency" and are actively involved in the coach's decision-making process.</b></p>	<ul style="list-style-type: none"> <li>▪ Users may be able to send all potential fine tuning for the system</li> <li>▪ The virtual coach should ask for a lot of "direct input" and use this input as directly as possible in their advice. What is your name? "Harry". "Hello Harry." is the most basic example.</li> </ul>
<p><b>2. User Feedback and development: Users trust the system, and actively provide feedback to the developers for improvements.</b></p>	<ul style="list-style-type: none"> <li>▪ Pro-actively ask for feedback e.g. "Did you like the recommendation I just gave you? Did you follow-through with the suggestion? Why/Why not?"</li> <li>▪ The "organisation" behind Council of Coaches could set up an open forum in which the advice is being co-developed with designers, developers, healthcare experts and users around the world.</li> </ul>
<p><b>3. Council of Coaches as catalyser: The Council of Coaches helps users to help identify their issues and motivates them to connect to real humans that may help them if needed. The application acts as an initiator for a higher quality of life with more person to person interaction.</b></p>	<ul style="list-style-type: none"> <li>▪ Indeed, I am a bit concerned that the user is left on his own to do self-management.</li> <li>• At the beginning ask the users to list key people in their network: family members, friends, GP etc. so the Council of Coaches can suggest to get in touch with specific</li> </ul>

	people rather than just say “Call a family member”.
<b>4. The good user: Everyone has a coach at home and take the advice if they want it and it is useful. The users are well informed, consenting, and critically compliant patient.</b>	<ul style="list-style-type: none"> <li>▪ This is obviously very nice, but very difficult to give specific guidance about.</li> </ul>

## 4.5 What users think – and how to consider it

The user studies conducted in WP2 were connected to the RRI process, yet in a less integrated manner than the exchange between the socio-technical integration and the stakeholder engagement. The outputs from the user studies did however find its way into the RRI process, framing engagement with elderly people about their tech habits, for example, in a very different manner than would have been the case had we not benefited from the results of the first user study (the diary study), which made us aware that many elderly people are just as informed and able to handle complex technology as their younger fellow citizens.

The proceedings and results from the work with users is described in D2.3, D2.4, D2.5, D2.6 and D7.7.



## 5 Conclusion

### 5.1 Grounded theory – building a hands-on method on experiences from COUCH

In this report the very diverse activities we have conducted throughout our responsibility work in the Council of Coaches project have been described. In place of grand conclusions, it has been the intention throughout to make each section contribute its own rounding off of the activities described. However, having reached the concluding section of the text thus leaves one additional outcome untouched. By conducting our process in the experimental and co-creative format we have done, letting empirical finding lead us to the next steps, looking forward as well as back, remembering to integrate horizontally (connecting objectives, everyday challenges, discoveries and concerns and projected outcomes) as well as vertically (connecting the consortium with users, stakeholders, the industry, market, research and patient organisations) we believe that by a veritable RRI-centred version of grounded theory, we have in fact created a new and unique, hands-on approach to collaborative management of responsible innovation in project work. We have named this our stiRRIng method – and we hope to be able to develop this further and have the opportunity to try it out in another project in the near future.

### 5.2 Lessons learned: Does StiRRIng work? A conversation with the consortium

The methodology we have launched and tested in this project is novel and experimental in character. We were – as we knew we would be – literally learning-by-doing. So, what did we learn from this process? Below are a few considerations voiced by members of the consortium.

1) A crucial dimension of making the approach ‘work’ – as we believe, we have, is that *all* members of the consortium have been involved in the discussions concerning responsibility. It is not just a few PIs having conference calls once in a while and then propagating it down the system. Everybody, whether they wanted it or not, have been included to think about these things and at least it is a fair assumption that they all take these discussions into account. People have been quite serious about it and remembered the discussions from one workshop to the next and put a lot of effort into thinking about things. It has also been due to the fact that we have not been talking on a very abstract level about e.g. regulatory frameworks or privacy laws or regulation – we have been talking about the thing that we are going to design and develop together, which was not always very clear what was (besides being a research project), so the discussions have revolved around doing what we were going to do, responsibly. So even for whoever may actually not originally have been very interested in the subject of responsibility, it was still worthwhile to participate in the discussions because they were about what exactly we were going to make. The whole idea of traveling around, meeting with people and trying to engage them has also the side-effect that after a while people just cannot resist being part of this. The stiRRIng process have been very much about not only making this work easier, but making it possible, in the first place, to talk about these things. To enable people to reflect on these things in a way that means something for them, and not just repeating all the keywords. Not perhaps in every line of coding that you write, but enough to influence your thinking.

2) The process influenced the project’s thinking in at least two ways. One the one hand there was these very practical issues that taught perhaps especially the younger researchers what shape RRI could take in these kinds of projects. On the other there were the more experienced researchers that had probably already ran into these kinds of things. There were examples of people in the project who, after reading the original document formulating the Vision plus its context and background, said that now they finally understood what people mean by RRI! That was an abstract, higher level thing, but it put things into place for more experienced researchers. The two-level approach was really what brought everything together in the end. There was something in it for everyone.

3) There was already a demand for hand-on approaches at the time of the call, which the project responded to. It was a little bit of a jungle to navigate but finding a way through via a concrete connection was a real achievement. From a process kind of view, it was e.g. quite exemplary to move forward in the manner where around halfway through the process, there was a feedback loop back to the boundary

(sleeper) issues again to catch up. It signalled that this is a project evolving, and taking it seriously, checking whether what looked important from the beginning was still important and what other issues may have arisen. It made the work more fluent, more realistic, and also more practical. Less tunnel vision. It kept it more open and alive. Making the process adapt to the actual work going on was crucial in this respect.

4) In terms of practicalities and roles, it was very helpful to have an external partner (the DBT) carry out the conversations. Having a designated expert on these matters being the guardian of these aspects rather than a technically involved partner wearing yet another hat made it much more effective than having an internal project manager running the process. By in this way making it more official and having experts to discuss all the details was a very clever move, seen in retrospect. It also resonated better in the project.

5) The stiRRIng process may not work for all kinds of projects. Our consortium was very open to new things and they were relatively young (many PhDs). Other projects, where people are perhaps more technical and less social, may not respond as well to the process as was the case here. But perhaps it is not possible to simply copy-paste the entire method onto other projects. This is yet to be explored.

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