

The market access of innovation in health care: insights from EC-funded research

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Abstract

Purpose – This study aims to offer novel insights on how industrial marketing might contribute to bringing innovations to market in the peculiar case of health care. This study aims at shedding first light on how the alignment between dissemination and exploitation activities might contribute to bringing to market innovations developed by public–private partnerships funded by the European Commission (EC).

Design/methodology/approach – The theoretical development comes from an inductive research design based on the 42-month pan-European H2020 research project NESTORE aimed at developing an integrated portfolio of innovations for the healthy aging of European citizens.

Findings – This study advances the theory and practice of industrial marketing in health care by conceptualizing an actionable method to align dissemination and exploitation activities within EC-funded projects, facilitating that innovations will go to market. The method is composed of five phases. First, an external analysis to define market opportunities and users'/stakeholders' needs. Second, an internal analysis to identify the most promising exploitable outputs. Third, scenarios crystallization to define the most suitable scenarios (business models) to bring the selected exploitable outputs to market. Fourth, exploitation and dissemination alignment through the identification and involvement of the most relevant stakeholders. Fifth, scenario refinement and business plan.

Originality/value – This study is relevant because many EC-funded projects still fail to move innovations from labs to market, thus limiting the benefits for the European citizens and the competitiveness of Europe with respect to the USA and China. Although this relevance, past studies overlooked the peculiar context of EC-funded innovation projects, privileging pharmaceutical and biomedical companies. This study advance theory and practice of industrial marketing in health care.

Keywords Innovation, Health care, Business model, Platform, Market access, Silver economy

Paper type Research paper

1. Introduction

The still ongoing COVID-19 emergency has shown clearly the fragility of the health-care systems of the most developed countries and the need to rethink how care delivery is organized and managed. The combination of the effects of this pandemic flu with the challenges that policymakers and professionals were already facing in the past years – for example, ageing population, growth of chronic diseases, shrinking of the gross domestic product (GDP), increased pace of technological innovation, consumerization and digital transformation (Braithwaite *et al.*, 2018) – has created a “perfect storm”. As shown by some recent studies on the business-to-business (B2B) marketing responses to the COVID-19 crisis (Crick and

Crick, 2020; Kang *et al.*, 2021), the theories and tools developed by scholars of industrial marketing might offer significant opportunities to face this perfect storm in health care.

In such a context, the capability to accelerate the market access (MA) of those innovations – products, services, business models, etc. – that proved to be value-for-money is a priority on

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the agenda of both policymakers and scholars of innovation management, marketing and health policy (Elton and O'Riordan, 2016). Past research has acknowledged that industrial marketing plays a pivotal role in the success (or unsuccess) of the adoption and diffusion of innovations within B2B networks (Frambach, 1993; Makkonen and Johnston, 2014; Woodside and Biemans, 2005). In the health-care sector, these activities are usually included in the MA strategy implemented by pharmaceutical and MedTech companies, which defines the set of activities and processes to develop to ensure that new products (drugs, medical devices, other technologies) are made available and adequately priced in a specific health-care system (Thomas et al., 2018).

Traditionally, MA adopts a product-centred approach, focusing the efforts on push marketing strategies to ensure a successful launch on the market (Wenzel et al., 2014). In this view, most of the marketing effort is directed to clinicians leveraging the principle of “shared voice” (McClearn and Croisier, 2013). More recently, in the attempt to limit the budget impact and address uncertainty regarding the investment in new products, MA focused on the development of entry agreements also known as innovative pricing agreements (Dunlop et al., 2018; Ferrario and Kanavos, 2013; Jarosawski and Toumi, 2011). The objective of these agreements between pharmaceutical/MedTech companies and health-care authorities and policymakers is to share the financial risk related to the launch of new products supporting the achievement of a fair reimbursed price and a favourable recommendation for prescribing (Ferrario and Kanavos, 2013; Kanavos et al., 2017; Klemp and Frønsdal, 2011). Thus, the introduction of new products to the health-care market is usually a process involving a limited number of stakeholders, supported by the adoption of traditional marketing strategies in the final stages of the product development process or preventive price agreements to reduce risks. However, this MA strategy may not be suited to the raising complexity of this sector. This is not just due to the before mentioned current technological and economic conjuncture but also to the need to develop (with and for) and subsequently demonstrate the value of new products to a plurality of interlocutors (Guercini et al., 2020; Kumar et al., 2014). These include a new and diverse set of stakeholders that have emerged over the past years and gained dominant positions, generating the need for a new “share of voice” (Thomas et al., 2018). In this context, MA requires good and deeper interactions with Key Opinion Leader (KOL) clinicians, agencies/authorities, hospital managers, pharmacists, leaders of governing authorities, Health Technology Assessment (HTA) Committees, insurance managers, doctors involved in clinical governance, patient associations and influential associations (Thomas et al., 2018). Over seeking the involvement of this intertwined and interlocked network of stakeholders, MA should be strictly integrated with research and development (R&D), commercial and marketing activities establishing an inter-functional strategy to favour the access, adoption and recognition of the value of new products in the health-care sector (Guercini et al., 2020; Kumar et al., 2014; McClearn and Croisier, 2013). Furthermore, it should be not limited only to a specific phase of the product life-cycle (Guercini et al., 2020; Kumar et al., 2014). More broadly, when developing a MA strategy in health

care, great attention and critical judgement should be paid to address the peculiarities of this regulated, professional and knowledge-intensive ecosystem (Schivone and Simoni, 2019).

Despite these claims, little has been said on how an effective MA strategy should be organized and developed moving further traditional marketing approaches. Particularly, there is consensus around the importance of involving relevant stakeholders, but not on how to recognize and engage them, what their roles and responsibilities should be, and how to make the most out of their engagement in MA strategies. To the best of the authors' knowledge, indeed, the academic discussion around stakeholder integration remains an open and still debated question (Pera et al., 2016). Although the relevance of multiple stakeholder engagement is becoming increasingly evident, addressing multiple prospective can be particularly challenging especially in highly complex networks that involve both private and public actors such as public-private partnerships (Babacan, 2021). Firstly, the common ground of the contributions recognizes the stakeholder identification process particularly challenging specifically when considering “accessibility” that sometimes is strongly influenced by rules, regulations or potential conflict of interests (Citron, 2012). Other pitfalls could also occur in the interaction phase during the actual information exchange and engagement and are strongly dependent on different objectives, needs but also norms or communications and interaction methods (Juanola-Feliu et al., 2012). Moreover, being the reference context extremely dynamic, the relevance of different stakeholders may vary over time. Therefore, literature from the network analysis suggests that managing multiple stakeholders requires a set of robust capabilities (Vaquero Martin et al., 2016) to address these challenges.

Against this limitation, this study aims at shedding novel light on how MA strategies should be effectively organized to facilitate the MA of innovations in the health-care market and increase the “market-product fit” by also involving the most relevant stakeholders. In the light of this, this study aims at addressing the following research question:

RQ1. How dissemination and exploitation activities can be aligned to improve the market-product fit for innovative solutions in health care?

Answering this question is relevant because the potential gap between the needs of the market – and the most relevant stakeholders – and the technical choices – and advancements of the products/services – is a critical obstacle that might limit commercial success. This is particularly evident in the case of pan-European H2020 research projects that are funded by the European Commission (EC). EC-funded projects are typically characterized by high innovation potential, partnership centrality, transnationality, organizational variety and diversity, around a 36-month duration, flexible decision-making hierarchy and a high degree of risk uptake (Veugeliers et al., 2015; Lettieri et al., 2015). We argue that these specific features create a context of unique complexity but also fertility to advance both theory and practice of industrial marketing in health care with a focus on the development of a MA strategy to increase the “market-product fit”. From the point of view of the EC, MA strategies should be able to better connect – and align – “Exploitation” and “Dissemination” (E&D) activities, meaning

the capability to engage the most relevant stakeholders into constructive conversations aimed at understanding their needs and concerns, to address them into the commercialization strategy of the exploitable innovations.

This study offers novel insights to further this debate crystallized from the experience matured by the authors within the H2020 pan-European NESTORE project – Novel Empowering Solutions and Technologies for Older people to Retain Everyday life activity. Within the period of the research project (42 months), the authors developed, applied and validated an integrated model to support a MA strategy – named “E&D Canvas” to meet the expectations of the EC. In this study, the E&D Canvas, its components, their interdependence and temporal sequence are presented and discussed in light of how MA strategies might be designed to improve the “market-product fit” of health-care innovations and facilitate their commercialization.

This paper is organized as follows. Firstly, the authors will introduce the theoretical background of this study deepening the concept of MA of innovations in health care, its evolution over time and its application in different organizations. Then, the main characteristics of EC-funded research projects and the pan-European NESTORE research project will be pointed out to better contextualize the empirical setting. The research design will be described in the following section. Then, the proposed framework for aligning dissemination and exploitation activities will be described step by step as the main result of this study. Finally, the last section will summarize the theoretical and empirical implications.

2. Market access

In health care, MA has been defined as “the set of strategies, activities and processes that pharmaceutical and biomedical companies develop to ensure that their products are made available and adequately priced in a specific health-care system” (Thomas *et al.*, 2018).

The traditional MA approach is a linear process that involves – beyond the manufacturers – payers, financial intermediaries, health-care providers, trade associations and regulatory bodies (Stremersch and Dyck, 2009). In this view, physicians are the main target of marketing activities aiming at guaranteeing greater product uptake (McClearn and Croisier, 2013). Activities mainly include detailing (the direct promotion through representatives who personally inform physicians about new products) and, less frequently, sampling and journal advertising (Hilsenrath, 2011). Detailing involves the process of communicating the new product and its benefits to health-care professionals using either personal or communication skills and referencing the scientific evidence from the literature (Alkhateeb *et al.*, 2009; Banerjee and Dash, 2011). Past studies showed that physicians are not interested in engaging with commercial representatives as they may not consider these interactions as value-adding (Hilsenrath, 2011; Morgan and Link, 2010).

MA is traditionally based on a product-centred approach; with pharmaceutical and biomedical companies first developing a finished product and, only afterwards, applying push marketing strategies to launch it to the market (Wenzel *et al.*, 2014). After all, historically, there is a correlation

between higher marketing exposure of health-care professionals and sales for pharmaceutical companies (Lublóy, 2014).

More recently, MA started focusing on pricing and reimbursing activities. Formal arrangements between health-care payers and manufacturers started to rise, especially in the USA and European pharmaceutical sectors (Dunlop *et al.*, 2018; Ferrario and Kanavos, 2013; Jarosawski and Toumi, 2011; Nazareth, 2017). These consist of finding a compromise on price and reimbursement status, HTA recommendation and/or formulary listing (Ferrario and Kanavos, 2013; Kanavos *et al.*, 2017; Klemp and Frønsdal, 2011). The aim is to share the financial risk caused by the uncertainty surrounding the introduction of a new product, which is related to the budgetary pressure (due to years of economic downturn) of health-care payers, growing costs of innovation development for manufacturers and increased severity of the regulatory bodies (Nooten *et al.*, 2012). These agreements can take different forms including discounts, price-volume agreements, outcome guarantees, coverage with evidence development and disease management programmes (Kanavos *et al.*, 2017), as well as a variety of names such as risk-sharing agreements, performance-based agreements, patient access schemes, innovative pricing agreements, entry agreements or MA agreements (Klemp and Frønsdal, 2011). Two are the main type of emphasis placed on MA agreements, namely, financial and clinical performance. Regarding the former, it refers to those mainly related to financial aspects and deal with topics such as annualized rebates, listed price discounts or price-volume agreements. While the latter puts the light on the clinical performances in terms of per-patient outcomes or evidence collected through real-world studies (Dunlop *et al.*, 2018).

Evidence from Europe shows a relevant uptake of these agreements indicating that the impact on budget targets in more than 75% of the cases, either alone (42%) or together with cost-effectiveness (16%). Moreover, from the continent perspective, the favoured and more adopted one is price-volume (40%), while requirements for data collection (29.4%) and limited access to eligible patients (12.6%) are awarded second and third (Ferrario and Kanavos, 2013).

Furthermore, in a recent survey in the five biggest European markets (i.e. Germany, UK, France, Italy and Spain), payers expressed a positive attitude to MA agreements and an expected increase in their use in the future (Dunlop *et al.*, 2018). However, despite the increasing uptake of the MA agreements in several markets, there are critiques about the fact that such schemes may represent “quick-fix” solutions (Kanavos *et al.*, 2017) and they may introduce perverse incentives into MA (Jarosawski and Toumi, 2011), producing a trifling refund (Navarria *et al.*, 2015). To avoid these pitfalls, MA agreements should be integrated into a comprehensive process of managed entry of new products in health care that starts with horizon scanning activities, proceeds to forecast, HTA, pricing and reimbursement, and continues with post-marketing studies and surveillance (Kanavos *et al.*, 2017).

In the past year, the MA landscape has evolved considering mainly to two factors (Kumar *et al.*, 2014; Thomas *et al.*, 2018; Schiavone and Simoni, 2019): on one hand the increasing of the health-care costs that are strongly related to the ageing of the population and the growing of the chronic disease prevalences, while on the other the pricing and reimbursement

environment, as they are strongly dependent on the health care authorities that are narrowing the spaces for new products. In this scenario, a new and diverse set of stakeholders have emerged over the years leading to increasing complexity of the product access in the market by shaping an interrelated network around MA (Kumar et al., 2014; Thomas et al., 2018). This includes agencies/authorities and policymakers at different institutional levels (national, regional and local), clinicians, KOLs, patients and patients' associations, hospitals, pharmacies and insurance companies, as well as scientific associations, universities and research centres, intermediaries and employees in the health system.

Consistent with the previous literature, all of these new actors stand out to have their interests, and unique perceptions and concerns about the access of a new product in the market (Kumar et al., 2014). Each of them is indeed interested in one or the other aspects of MA and their involvement may vary considerably by the area of investigation. Moreover, they are usually involved at different levels. For example, the end-users (i.e. the patients) are usually the ones who request equipment purchases based on medical needs, therefore, they are more concerned about the effectiveness of the solutions. While health authorities or other government bodies also pursue the objective to maintain the financial equilibrium of the local, regional or national system. Moreover, the health-care system is even complicated by a board decentralization of decision makers (Leone, Schiavone and Simoni, 2021) that added complexity to the process by empowering enormous differences in the assessment criteria adopted at different levels.

Therefore, while on one hand understanding and engaging with the different stakeholders is reported as a key success factor for MA functions, on the other, their involvement in the activities and the effective engagement with them is recognized as one of the unique challenges, as managing their complexity in both interconnections, and objectives and needs may be extremely critical.

Moreover, Leone et al. (2021) in their work assessed that building trust and solid relationships among stakeholders have the potential to greatly influence the future of the product, especially when considering novel solutions.

In the light of the above, MA activities should be seen as a process aimed at accessing a plurality of stakeholders paying strong attention to empowering specific tools and tactics to strategize, plan, implement and monitor engagement activities for the new stakeholders (Koçkaya and Wertheimer, 2018; Thomas et al., 2018). For this purpose, scholars suggest that MA should involve the integration of different organizational units within the same company (Data and Mariani, 2015), especially R&D, marketing and commercial activities. Thus, MA requires relevant organizational skills, consideration of contractual and legal issues, and, most important, the capacity to manage networks of relationships (Falotico and Mariani, 2014). Furthermore, "MA should not be limited to a specific phase of the product life cycle or to a set of tactical activities to respond to obstacles and barriers actively" (Guercini et al., 2020). MA should leverage advanced and integrated marketing approaches (Schiavone and Simoni, 2019; Wenzel et al., 2014), targeting more than a few restricted groups of stakeholders (such as physicians) and going beyond simple price agreements with payers. Ultimately, following the definition proposed by

Guercini et al. (2020), MA can be meant as an inter-functional strategy aimed at access to the market by creating novel forms of collaboration and dialogue with the different stakeholders involved. This is possible because of the use of novel tools able to demonstrate the therapeutic, economic and social value of new products.

In this perspective, Pilon and Hadjielias (2017) studied the dynamics enabling the strategic account management approach to function as a value co-creation MA model aimed at sustaining long terms relationships with the main stakeholder in the pharmaceutical and health-care industries. Schiavone and Simoni (2019) instead, studied the strategic industrial marketing approaches, such as educational activities for the stakeholders, simulation of the innovation's impact on the entire system and creation of a MA unit, suited for the MA of new products in the highly regulated health-care market.

To the best of the authors' knowledge, besides these few examples, MA is still a neglected topic in industrial marketing literature. No models for the development of an effective MA strategy encompassing specific methods, tools and tactics to strategize, plan, develop and monitor the engagement of the interrelated network of different stakeholders involved in the MA has been spotted. Considering this, past contributions are characterized by two main gaps. On the first hand, they limit their investigation to the view of end-users overlooking the needs of other groups of relevant stakeholders (e.g. regulators, payers, hospital managers and professionals, developers, standard makers, etc.). On the other hand, they dealt with dissemination and exploitation as mainly separate activities, neglecting their interdependence and the consequent need for approaches that are interactive and not linear. The need of harmonizing the point of view of a plurality of relevant and diverse groups of stakeholders – which directly or indirectly may impact the MA process of innovations in health care – requires the continuous alignment of the strategies for dissemination and exploitation to increase the product-market fit and the success of the future commercialization plan.

Against these limitations, this study aims at narrowing them by shedding novel light on how dissemination and exploitation can be aligned within EC-funded research projects and improve the design of effective MA strategies for introducing innovations in health care. The next section will detail why EC-funded research is a fertile empirical setting where to gather original insights to narrow the literature gaps pointed out above about the access of innovations to the health-care market.

2.1 European Commission-funded research

The EC represents nowadays one of the leading innovation boosters in health care (European Commission, 2014) as a result of the significant funding efforts paid overtime to sustain research as well as the generation of public-private partnerships (PPPs). The research programme "Horizon 2020" (H2020) made available almost €8bn for health-related innovations. PPPs – also called Consortia – are formed by several partners from different countries, industries and academia. Consortia tackled relevant challenges such as population ageing, silver economy, non-communicable diseases and chronic care, innovative products and services, digital opportunities and social innovation (European Commission, 2019). EC-funded projects typically have the following characteristics (European

Commission, 2014). Firstly, they promote partnerships: organizations across different sectors and regions come together to develop breakthrough solutions; this means that a large and complex ecosystem of different stakeholders is created and must be properly managed. Secondly, they are transnational: organizations are from different countries and the project must create value for all European citizens level, therefore it has to address different national contexts (e.g. markets and regulations). Thirdly, they are very innovative: the project usually leads to the development of new knowledge or a new technology embedded in products/services that require years for prototyping, testing, demonstrating, piloting, scaling-up, etc. The complexity of the context is enhanced by different factors that deal with the length of the projects, the variety in organizational and decision-making hierarchy (often not clearly defined) or again the missing of a clear direction for the innovation. Due to this complexity, many EC-funded projects seem to fail in bringing the innovations to the market, thus having a limited capability to capitalize on their innovation potential and hampering the competitiveness of Europe in the industry of health care (Veugelers et al., 2015).

For this reason, the EC identified the necessity – to bring innovation to the market – to design and implement more effective MA strategies for every EC-funded project (European IPR HelpDesk, 2016). These MA strategies should be based on the principle of E&D. Exploitation refers to the actual usage of project results for commercial purposes, while dissemination means sharing project results with the most relevant stakeholders to facilitate access to the health market, adoption by relevant providers, and rapid diffusion among the health-care eco-system (European IPR HelpDesk, 2016). An effective E&D strategy leads to outcomes such as the launching of the innovative products or services to market, the transfer of results and best practices to different and broader contexts, the potential tailoring to the needs of others, the continuation after the funding period has finished, the influences on policy and practice, as well as serving the public good (Siakas et al., 2012). Therefore, in the context of EC-funded projects, an effective E&D strategy is pivotal for the successful MA of innovation. Moreover, the development of a detailed and thorough E&D plan is a mandatory condition required to access the research funding (European Parliament, 2014).

2.2 The empirical context

NESTORE is a 42-month pan-European H2020 research project aimed at developing an integrated portfolio of innovations for the healthy ageing of European citizens aged 65+. The *fil rouge* among such innovations is the development of an innovative, personalized, artificial intelligence-enabled virtual coaching system able to generate and reinforce users' motivation about the improvement of nutrition, physical activities and social interactions to preserve their well-being.

The solution proposed represents an innovative cutting-edge innovation in the field of computer-based technologies for education, counselling and health behaviour training. A virtual coach is indeed a technology able to monitor the user's parameters and offer situational awareness giving feedback and encouragement matched to the user's cognitive and physical current state (Brandenburgh et al., 2014) while establishing a relationship with the trainee (Fasola and Mataric, 2013).

According to the latest in-scope literature, virtual coaches have the potential to maximize users' adherence to therapy resulting in a higher probability of reaching the goal of the program (Mastropietro et al., 2018). By leveraging on novel information & communication technology technologies, indeed, the solution proposed can gather users' data through a multi-parametric and multidimensional sensing layer and process them to generate personalized advice and coaching strategies in five domains (physical activity, nutrition, social, cognitive and psychological). More specifically, the technical complexity embraces three main layers. First a multi-domain unobtrusive monitoring system including wearable smart bracelets, environmental sensors, a smart scale and a sleep monitoring device. Secondly, the reasoning layer is composed of the intelligent decision support system able to analyze the seniors' behaviour and suggest personalized "pathways of interest" following the Health Action Process Approach. Thirdly, a multi-function tangible conversational agent that can assume different configurations to establish effective communication to engage users with personalized coaching activities. NESTORE wants to differentiate itself from the existing eHealth solutions, promoting healthy paths able to embrace wellbeing and health as a validated and multi-dimensional personalized system based on scientific knowledge. All the feedback and the coaching strategy provided, are indeed scientifically validated by the multi-disciplinary experts of the Consortium.

The NESTORE Consortium is a collaborative and complex network composed of 15 partners from 8 European countries covering different categories of stakeholders to ensure that a wide range of competencies (from project management to medical expertise and design technologies) (Table 1). The Consortium has a very strong research component with seven universities and two research institutions, while the industry is represented by three small & medium enterprises and one large corporation. Moreover, it includes also other institutions covering social and health aspects as well as communications and dissemination activities with a strong presence on the local territory and a strong link with the target communities. Committing the industrial component in the consortium represents an important opportunity to exploit the research results meeting the EC expectations.

The industrial partner indeed takes the chance of the NESTORE project to explore new frontiers expanding or consolidating their presence in a promising market segment. The ambition of the NESTORE Consortium was to develop a solution that could answer the urgent need for digital innovation in the sector of health and social care, giving a significant contribution to this transformation by introducing into the market a solution that addresses healthy ageing with a wide-reaching and integrated approach. The Consortium shared the vision that NESTORE might have a wide societal and economic impact, answering the expectations of the H2020 program. However, there were not clear literature-informed methods and practices that might help to address the creation of a commercial opportunity for such innovation that challenges what professionals and citizens think about healthy ageing and the role that artificial intelligence might play.

In this view, the NESTORE project offers a fertile empirical *locus* for extending what is known about MA strategies in health

Table 1 NESTORE consortium

Partner	Country	Type
AGE PLATFORM EUROPE	Belgium	Societal
CONSIGLIO NAZIONALE DELLE RICERCHE	Italy	Research
FLEXTRONICS DESIGN SRL	Italy	Industrial
FUNDACIO EURECAT	Spain	Industrial
FUNDACIO SALUT I ENVELLIMENT	Spain	Research
HAUTE ECOLE SPECIALISEE DE SUISSE OCCIDENTALE	Switzerland	Research
LA MERIDIANA DUE - SOCIETA' COOPERATIVA SOCIALE	Italy	Societal
LOUGHBOROUGH UNIVERSITY	UK	Research
NEOSPERIENCE SPA	Italy	Industrial
PREVENTIVE COLLECTIEF	The Netherlands	Societal
ROPARDO SRL	Romania	Industrial
SHEFFIELD HALLAM UNIVERSITY	UK	Research
TECHNISCHE UNIVERSITEIT DELFT	The Netherlands	Research
UNIVERSITAT DE BARCELONA	Spain	Research
UNIVERSITAT ZURICH	Switzerland	Research

care because of both the organizational complexity of a pan-European Consortium (Lloyd and Hartel, 2010) and the disruptive nature of the innovation proposed to the market.

3. Materials and methods

The authors adopted a single case study research design for this study. Small sample research is adequate to develop new theoretical insights about issues whose current understanding is still at an early stage (Yin, 2003). This can be obtained through the in-depth investigation of the peculiarities and determinants of the issue under inquiry (Lamberti and Lettieri, 2009). In this line of reasoning, Siggelkow (2007) argued that a single case study design can contribute to existing knowledge through the deepening or widening of the current understanding. Moreover, the inductive theory-generation, particularly used for health and social science research and evaluation (Thomas, 2006), is commonly associated with a “resulting model about the underlying structure of experiences and perceptions” derived from insight within the case (Thomas, 2006).

Within an inductive research design, the researcher is let free to adapt the investigation direction based on the need to generate meanings from the data set collected to identify patterns and relationships among the data and build an original theoretical understanding (Goddard and Melville, 2004). In inductive research, existing theory can be used to shape the research question to be investigated and identify the relevant variables to be explored and connected (Newman, 2003).

Being inductive research based on learning from direct experience, the authors considered this approach particularly fitting to the research context – i.e. the NESTORE research project – and to the development of MA strategies that might improve the “product-market fit” as well as the commercialization opportunities of innovations originated in pan-European research projects.

Novel knowledge has been collectively generated during the whole lifespan of the project (42 months) and crystallized during the periodic review meeting with all partners (every 6 months). The authors of this study chaired the scientific, E&D activities, and composed the so-called D&E Team. This responsibility provided them with a privileged observation

point about the design and implementation of a MA strategy that can improve the “market-product fit” and the commercialization success of the innovations generated within the NESTORE research project. In particular, they could investigate the linkage between dissemination and exploitation as recommended by the EC.

The insights – and the original framework for supporting the MA strategies for exploitable outputs generated in pan-European research projects and therefore named “E&D Canvas” – have been discussed, refined and validated through an expert opinion approach that involved four different groups of experts, with an inside-out design. Firstly, the insights were exposed to the judgment of the NESTORE Consortium partners to collect their opinions about its relevance, comprehensiveness and robustness. Secondly, the revised insights were exposed to the so-called Forum of Advisory Stakeholders (FAS) that is a permanent Advisory Board of the NESTORE project composed of representatives of the most relevant groups of stakeholders (e.g. advocacy groups of target users, health-care institutions, regulatory agencies, technology providers, health and social care professionals, etc). that every six months reviewed the main results generated by the Consortium. The engagement of the FAS allowed to broaden the scope of the perspectives – and of the comments – about the relevance, comprehensiveness and robustness of the insights generated by the D&E Team. Thirdly, the revised insights have been challenged by the appointed Project Officer and three nominated reviewers (two academicians and one entrepreneur). This round allowed us to read the insights from the perspective of the EC, the scientific community and the entrepreneurial field. Fourthly, the consolidated insights have been presented in three international exhibitions to a selected panel of potential investors.

These four rounds of expert opinion elicitation allowed the progressive refinement and final validation of the novel knowledge generated within the NESTORE research project as well as of the framework that has been developed to organize a MA strategy for health-care innovations generated within pan-European research projects that might improve the “market-product fit” through the linkage of E&D activities.

In the following section, the E&D Canvas is described step by step in detail. This framework represents the main results presented in this manuscript.

4. Results: a framework to improve “the market-product fit”

In the following section, the main results of the study are presented as a series of subsequential steps to improve the “market-production fit” of health-care innovations developed by in-depth investigation of the experience matured in the H2020 pan-European project NESTORE. Specifically, the paragraph is organized into four sections reflecting the four cardinal steps of the E&D Canvas, which are the following. Step I – market analysis, Step II – MA strategy definition, Step III – stakeholders involvement and Step IV – MA strategy refinement and business plan. For each phase, examples from the NESTORE research project are reported and included to improve the clarity and the robustness of the framework.

4.1 Step I: market analysis

In line with the body of knowledge about the MA, especially when solutions are at an early stage or in emerging markets (Kumar *et al.*, 2014), the analysis of the reference market is a fundamental starting point to develop a customized MA strategy overcoming the traditional push-oriented approach. This is particularly true in such a complex and highly regulated context as the health-care one is Schiavone and Simoni (2019), which implies a comprehensive understanding of the external context (Leone *et al.*, 2021). Accordingly, the first step of the E&D framework involves the analysis of the external landscape and covers both the “demand” and the “supply” side of the market. In line with the traditional approaches, this first step requires a mixed-method approach (Barrett, 1996) allowing the combination of evidence gathered from various sources of data to crystallize a more comprehensive picture of the external landscape.

4.1.1 The demand side

The demand side should be investigated by combining desk analysis about relevant final users’ characteristics and market research to gather an in-depth understanding of their needs and requirements. Including the “voice of potential user” in the market analysis is suggested in the literature to be a key point to collect the determinants of the potential users’ intention to use the solution (Bettiga *et al.*, 2020). Within the NESTORE project, the desk analysis was carried out on a panel of 11 EU countries collecting data made available by institutional reports and other secondary data sources about final users’ characteristics e.g. demography, health status and prevalence of the chronic disease, IT literacy focusing on the NESTORE target domains: nutrition, physical, social, cognitive and psychological well-being. Table 2 reports data for the three pilot-site Countries (Italy, Spain, The Netherlands) as an example.

The market research was based on a structured survey administered to a sample of over 700 seniors in two of the NESTORE pilot countries (Italy and Spain) aiming at collecting the “voice of potential users”. The survey was designed using two well-respected theoretical frameworks: the technology acceptance model (Davis, 1989) and the theory of planned behaviour (Ajzen, 1991). The most significant insights

are shown in Figure 1. Firstly, the perceived usefulness (PU) – i.e. the intrinsic motivation supported by the perception of the utility and expected benefit – resulted to be the most relevant determinant related to the intention to use (ITU) a virtual coaching system similar to NESTORE. The impact of the perceived ease of use (PEU) also resulted to be significant, suggesting the need to develop a system based on simplicity and implementing user-friendly interfaces. Furthermore, the analysis showed how the subjective norm – i.e. the social pressure exerted on potential users by certain groups of stakeholders (such as family and friends but also general practitioners and other health-care professionals) – has an indirect effect on the ITU. This confirms the importance to engage a conversation with these groups of stakeholders. IT Literacy (ITL) together with Health Literacy, in Italy, affects mainly the PEU. In Spain, the effect of HL was not significant, while ITL positively influenced the ITU, mirroring its effect on the PU. Finally, none of the control (socio-demographic) variables affected the ITU.

4.1.2 The supply-side

The supply-side should be based on the analysis of the competitive landscape.

Within the NESTORE project, the competitive landscape belongs to the wide digital health and well-being market, which includes several different products and services such as mobile apps to monitor physical activity or other behaviours, fitness wearable devices and integrated digital solutions, as well as different types of companies. For this reason, the competitive landscape was clustered using three distinctive categories:

- 1 integrated products and/or services like NESTORE;
- 2 Mobile Apps engaging users into a healthier lifestyle with a prevention objective; and
- 3 start-ups developing solutions for the well-being and healthy lifestyle by leveraging on digital technologies.

Information on products or services like NESTORE was collected systematically through a standard template interrogating different online databases. Because of the great number of apps developed and available on the two main platforms (i.e. Google Play Store and Apple App Store), for the Mobile Apps cluster, a systematic analysis was not feasible. For this reason, five main polar characteristics were used to narrow the scope of the analysis:

- 1 Free – Paid.
- 2 Medical – Health and Fitness.
- 3 No/basic coaching – Advanced coaching.
- 4 Mono-dimensional – Multi-dimensional.
- 5 Integrated with devices – Standalone.

Figure 2 offers a synoptic overview.

Concerning start-ups, a sample of about 1,580 start-ups (founded between 2015 and 2019) was collected using Crunchbase, one of the most reliable and updated data sets on start-ups. The keywords used on Crunchbase to conduct this research were “health care, mHealth, personal health, home health care”. The identified start-ups have been divided into 15 macro-categories. Figure 3 presents the areas where the start-ups mainly focused on the past years, proving a relevant interest for the domains covered by NESTORE: intelligent tools to

Table 2 Desk analysis on European countries (focus to pilot-site countries)

Physical	Italy				Spain				The Netherlands						
	Total population	Close to NESTORE target (55–64) Males	Close to NESTORE target (55–64) Females	NESTORE target (65–74) Males	NESTORE target (65–74) Females	Total population	Close to NESTORE target (55–64) Males	Close to NESTORE target (55–64) Females	NESTORE target (65–74) Males	NESTORE target (65–74) Females	Total population	Close to NESTORE target (50–64) Males	Close to NESTORE target (50–64) Females	NESTORE target (65+) Males	NESTORE target (65+) Females
BMI (%)															
Underweight	3.7	0.6	3.3	0.8	1.9	2.6	0.4	0.8	0.6	2.1	2.3	0.2	1.1	0	0.9
Normal	52.5	34.4	51	33.4	44	46.4	26	42.7	23.2	31.7	50	33	45.5	32.3	43.1
Overweight	43.8	65.1	45.7	65.8	54.1	51	73.6	56.5	76.3	66.2	47.7	66.8	53.4	67.7	56
Obese	10.5	16.7	14.7	15.1	16.7	16.2	24.3	21.3	22.5	26.9	12.9	16.2	17.6	14.6	20.8
Work-related physical activity (%)															
Heavy	6.8	9.8	4.9	3.1	1.7	3.2	3	1.3	0.7	0.4	NA	NA	NA	NA	NA
Moderate	28.1	29.5	33.9	23.9	31	16.7	19.9	16.1	17.3	11.7	NA	NA	NA	NA	NA
None or light	65.1	60.7	61.2	73	67.3	80.2	77.1	82.6	81.9	87.9	NA	NA	NA	NA	NA
	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES
Taking part in sports/physical exercise (>once a week) (%)	32	28	14	35	29	35	29	28	39	32	70	75	59	71	69
Nutrition															
	Total population	Close to NESTORE target (55–64) MALES	Close to NESTORE target (55–64) FEMALES	NESTORE target (65–74) MALES	NESTORE target (65–74) FEMALES	Total population	Close to NESTORE target (55–64) MALES	Close to NESTORE target (55–64) FEMALES	NESTORE target (65–74) MALES	NESTORE target (65–74) FEMALES	Total population	Close to NESTORE target (55–64) MALES	Close to NESTORE target (55–64) FEMALES	NESTORE target (65–74) MALES	NESTORE target (65–74) FEMALES
0 portions	23	19.7	14.8	14.8	12.2	25	20.4	11.9	14.7	11.2	45.9	48.8	33.8	36.1	24.2
1–4 portions	65.1	69.1	68.1	68.1	68.5	62.6	64.5	69.7	70.2	69.3	29	28.1	36.5	33.7	38.1
5 portions or more	11.8	11.2	17.1	17.1	19.4	12.4	15.1	18.4	15.2	19.5	25	23.2	29.8	30.1	37.7
Frequency of fruit (%)															
At least once a day	74	80.3	80.6	80.6	85.3	66.7	72.6	81	80.2	84.2	41	38.9	54.8	53.4	65.1
1–3 times a week	11.1	10.8	7.4	7	4.9	16.3	13.8	8.9	7.4	6.7	20.9	20.2	15	15.6	11.3
4–6 times a week	12.7	11.6	10.1	10.3	8	12.6	10.5	7.7	10.7	7.8	27.6	28.6	22.6	21.4	16.7
Never/occasionally	5.3	3.6	2.1	2.1	1.8	4.4	3.1	2.3	1.7	1.3	10.4	12.3	7.6	9.6	6.8
Alcohol consumption (%)															
Every day	14.1	28.1	10.3	38.3	16.6	15.3	41.7	13.2	44.7	13.2	NA	NA	NA	NA	NA
Every week	24.4	29.9	17.2	24.1	11.4	22.3	20.9	18.4	16.1	9.6	NA	NA	NA	NA	NA
Every month	20	18.5	17.6	14.3	12.2	18.8	12.5	15.2	10.1	11	NA	NA	NA	NA	NA
Never or not in the past 12 months	32.8	16.3	44.2	17.1	50.2	31.3	18.5	40.4	21.1	52.1	NA	NA	NA	NA	NA
Social															
	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES	Total population	Close to NESTORE target (50–64)	Close to NESTORE target (65+)	MALES	FEMALES
Face-to face contact with family members or relatives (> once a week)	84	86	86	81	87	77	77	82	75	79	75	75	79	73	76
Face-to face contact with friends or neighbours (> once a week)	87	85	87	86	88	90	88	93	91	90	87	84	87	87	88
Phone/internet contact with family members or relatives (> once a week)	81	80	80	77	85	85	82	86	80	90	85	84	82	81	90
Phone/internet contact with friends or neighbours (> once a week)	76	65	76	74	77	75	72	53	77	73	73	66	57	70	76

(continued)

Table 2

	Italy				Spain				The Netherlands						
	Total population (16+)	Close to NESTORE target (55–64)		Total population (16+)	Close to NESTORE target (55–64)		Total population (16+)	Close to NESTORE target (55–64)		Total population (16+)	Close to NESTORE target (55–64)		Total population (16+)		
		Males	Females		Males	Females		Males	Females		Males	Females			
Cinema/Live performances/cultural sites/attending living sports (people with no activity limitation) (%)															
Cinema (1–3 times)	25.3	19.5	16.7	10.5	7.4	12.6	11.3	12.9	3.5	5	28.7	19.5	20.2	11.5	10.9
Cinema (+12 times)	5.1	2.6	2.5	1.7	1.4	3.4	1.2	1.9	0.4	0.9	4	1.7	0.9	0.9	0.5
Theatre and concerts (1–3 times)	22.2	16.6	19.1	10.8	11.2	14.5	14.7	12.5	6.5	8	36	30.9	30.5	23.8	19.9
Theatre and concerts (+12 times)	1.3	1.2	1.1	0.8	0.8	1.3	1.1	1.8	0.5	0.8	2.6	4	3.5	1.4	2.2
Cognitive	Total population	Close to NESTORE target (≤64)	NESTORE target (≥65)	NESTORE target (≥65)	Total population	Close to NESTORE target (≤64)	NESTORE target (≥64)	NESTORE target (≥65)	NESTORE target (≥65)	Total population	Close to NESTORE target (≤64)	NESTORE target (≥65)	NESTORE target (≥65)	NESTORE target (≥65)	NESTORE target (≥65)
Prevalence of dementia (%)	2.09	0.04	0.05	0.64	1.36	1.75	0.04	0.05	0.56	1.11	1.47	0.04	0.05	0.46	0.92
PSYCHOLOGICAL	Total population	Close to NESTORE target (50–64)	NESTORE target (65+)	Close to NESTORE target (50–64)	NESTORE target (65+)	Total population	Close to NESTORE target (50–64)	NESTORE target (65+)	Close to NESTORE target (50–64)	NESTORE target (65+)	Total population	Close to NESTORE target (50–64)	NESTORE target (65+)	Close to NESTORE target (50–64)	NESTORE target (65+)
Satisfaction with life (1–10)	6.6	6.6	6.4	6.6	6.6	7	6.6	7	6.9	7	7.7	7.7	7.7	7.7	7.7
Happiness (1–10)	6.8	6.9	6.4	6.8	6.8	7.3	6.9	7.2	7.3	7.3	7.8	7.9	7.7	7.8	7.8
Perceived health status as good or very good (%)	81.6	67	33	71	65	73	63	48	79	68	73	69	64	76	70
Have felt lonely (%)	7.2	6	13	6	8	6	11	5	5	7	3	2	6	2	4
WHO-5 mental well-being scale (%)	59.4	60	52	61	58	68	63	63	70	65	65	67	70	68	63

Figure 1 Statistical results from the survey administered in Italy and Spain

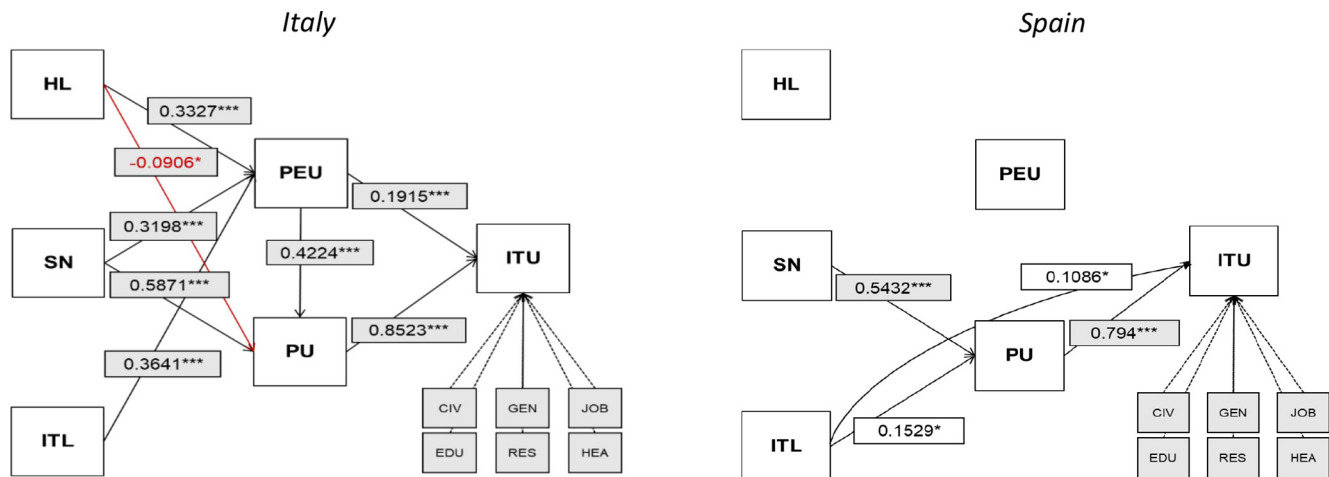


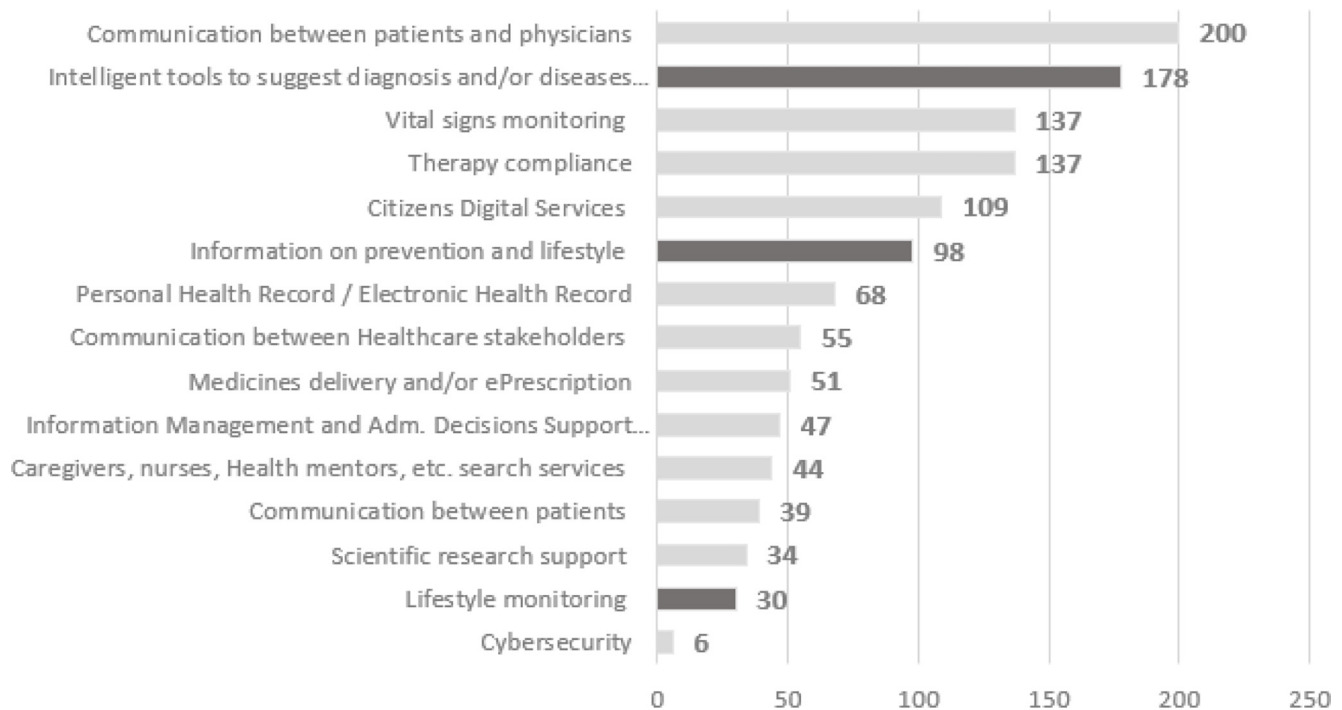
Figure 2 Health app polar type classification – relevant examples are displayed

App's name and logo	Payment	Category	Coaching	Dimensions	Equipment
LUMOSITY	Free	H&F	Basic	Mono	Stand alone
MIND GAMES	Free	H&F	Basic	Mono	Stand alone
ENDOMONDO	Free	H&F	Advanced	Multi	Stand alone
HRV4 Training	Paying	H&F	Advanced	Mono	Integrated with devices
Calorie Counter	Free	H&F	Advanced	Mono	Stand alone
Lose It!	Free	H&F + Medical	Basic	Mono	Stand alone
WYSA	Free	H&F	Advanced	Mono	Stand alone
Headspace	Free	H&F	Basic	Multi	Stand alone
HealthLab Diabetes	Free	H&F + Medical	Basic	Multi	Stand alone
ETERLY	Free	H&F	Advanced	Multi	Stand-alone OR integrated with devices
Fitbit	Paying	H&F	Advanced	Multi	Integrated with devices
Lark	Free	H&F	Advanced	Multi	Stand-alone OR integrated with devices

suggest diagnosis and/or disease management, information on prevention and lifestyle and lifestyle monitoring with, respectively, 178, 98 and 30 start-ups identified. Furthermore, the median value of the funding amount for each macro-category of start-ups was also computed. The macro-category “intelligent tools to suggest diagnosis and/or disease management” collected a median value of funds around \$2,560,000, “Information on Prevention and Lifestyle” around \$1,340,000 and “Lifestyle monitoring” about \$1,335,000. The median value of funds jointly collected by the three domains covered by NESTORE is aligned to the budget the EC set for the NESTORE project.

After collecting all the necessary information on the competitive landscape, the overall competition has been analyzed along two main dimensions: digitalization (i.e. the extent implementation of digital technologies) and personalization (i.e. tailoring coaching activities). The latter describes all the different existing ways in which seniors can get information, advice, motivation or incentive, considering the five well-being dimensions covered by NESTORE. Therefore, coaches have been clustered in:

Passive inputs: solutions characterized by no/basic personalization (users receive information but no feedback from the instructor/author/speaker) and no digitalization. This

Figure 3 Distribution of start-ups against the macro-categories

category includes newspapers, magazines, public events, advertising, informative brochures.

Quantified self: no personalization but digitalization supported by the use of mobile devices, apps and wearable technologies (e.g. basic mobile apps, app + devices for self-measurement; common wearables including fitness trackers, smartwatches).

Coach next door: advanced personalization but no digitalization. The coach knows the trainee and provides customized services, but digitalization is not supported. Examples are personal trainers, integrated training centres, nutrition and wellness centres and gyms.

Virtual coaching: users receive information, motivation and feedback from the instructor that provides a customized service reinforced using mobile devices, apps and wearable technologies that can track activities (i.e. NESTORE category).

Subsequently, further analysis and benchmark focused on the competitors belonging to the virtual coaching cluster; the main results of the positioning are presented in [Figure 4](#).

4.2 Step II: market access strategy definition

Reflecting on the experience of the NESTORE project, we suggest that the definition of the MA strategy should be grounded on two main axes of diversification before setting the other strategic levers through a detailed business plan. For NESTORE, starting from the main results of the market analysis described in the first step of the E&D Canvas, the level of integration along the value chain and the type of revenue stream were used for this purpose. The first is mainly related to the “openness” towards external players and

suppliers of physical products/services encompassing the possibility to transform NESTORE into an interoperable platform able to collect and digest data from different devices and services.

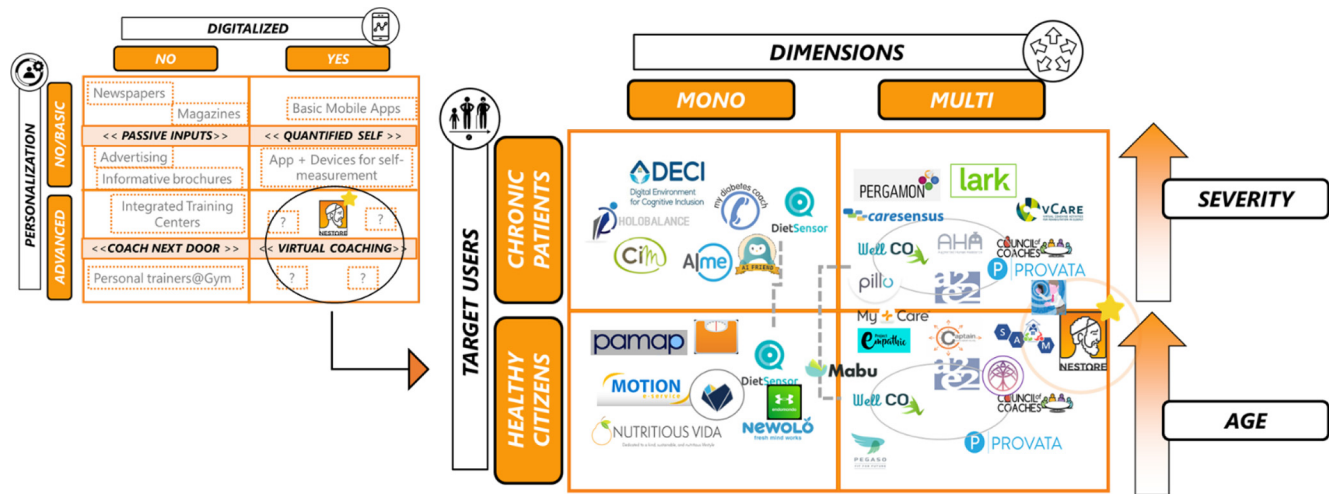
For the revenue stream, two main possibilities were considered:

- 1 freemium for the users (or with small co-payment) with a third party that pays for the service – it may be the case of public health authorities that intend to offer NESTORE to their citizens – or for the data (e.g. companies that are interested in aggregated data on lifestyle behaviours for both research and commercial purposes); or
- 2 and out-of-pocket paid by users.

4.3 Step III: stakeholders' involvement

The fourth step is the involvement of the most relevant stakeholders to support the MA strategy definition and validation. For this purpose, in the NESTORE project, the FAS was established. The FAS encompassed a pool of ten experts with different affiliations and backgrounds (such as health care, business and third age advocacy groups representatives, consumers, informal careers and researchers) who provided external advice and feedback across the lifespan of the project. The FAS advised on key technical issues, business and market directions, as well as the drafting of ethical and policy recommendations with a once-a-year dedicated meeting with NESTORE partners and frequent correspondence (e-mail exchanges, webinars, conference calls, etc.).

Figure 4 NESTORE benchmarking matrix



We also argued that a successful MA strategy is strongly dependent on the capacity to engage a conversation with those groups of stakeholders that more than others are affected by the introduction of the innovation and might determine the results of the MA strategy. For this reason, a large round of one-to-one structured interviews with more than 20 relevant stakeholders was carried out in the 3 NESTORE pilot-site countries (Italy, Spain, The Netherlands). To better address the interviews, the Consortium proposed six main categories of stakeholders that might concur in the creation, implementation and diffusion of NESTORE.

Payers: They are the actors potentially in charge of the payment and distribution of the NESTORE solution. As already stated, NESTORE has a high potential either as a B2B or business-to-consumer (B2C) business model. Payers include health authorities, insurance, pharmaceutical and biomedical companies. This group of stakeholders may provide insights on the price-reimbursement policy by assessing the clinical value of the novel solution while estimating the budget availability. Moreover, payers can play a crucial role in influencing the behaviour of end-users behaviour for the product.

Investors/funders: Engaging in a conversation with investors and funders such as the EC, institutional funds, private funds and business angels is key since they allow the understanding of the challenges of the market as well as the growth potential of both the solution and the ecosystems. Moreover, their role is of paramount importance in the further development of the solution and to implement the exploitation strategy, as these actors may provide NESTORE with the financial resources for the development of the designed solution supporting its actual introduction in the market.

Channels: They represent the pathways through which the NESTORE target segment could be reached out. They are responsible to ensure all appropriate final users have rapid and continued access to the solution. To design the NESTORE ecosystem, different channel options have been considered clustering them into physical channels, such as pharmacies and drug stores, tech retails, gyms and fitness centres and virtual channels such as e-commerce. These different actors have the

potential to influence product accessibility, therefore, engaging a conversation with them allows the Consortium to understand from the very first beginning their dispensing behaviour ensuring the most suitable choice and positioning.

Influencers: Influencers could create a network effect around the solution. Their influence can be noted from two different angles. Some stakeholders (e.g. physicians or third age advocacy groups), indeed, may influence the market and the final users' perception by effectively addressing the communication of the novel solution. On the other side, they can also shape and affect, even if in a not-direct manner, health-care policies guidelines and price decisions. For NESTORE, this category includes mainly physicians and other health-care professionals, third age advocacy groups and more generally the mass media.

Service providers and manufacturers for digital care solutions: This group of stakeholders was included since, as previously described, NESTORE could operate as an open solution. Therefore, engaging in a conversation with them helps the Consortium to understand other players' behaviour as well as the main determinants to develop joint solutions to offer to the market.

Standard makers: This group of stakeholders is the one with the highest prominence, as their role in the ecosystem is to shape the health-care policies and guidelines. They are also responsible for determining the price and reimbursement of products, services and treatments. For NESTORE this category includes scientific communities, health authorities, technology privacy or ethics standard makers who are involved in formulating policies. Including this category allow the Consortium to assess the compliance of the solution with the national and international regulatory framework and eventually to engage a joint work with them to develop and shape novel guidelines and evidence.

The main outcomes provided by the different stakeholders (both FAS and through the interviews) related to the definition and fine-tuning of the MA strategy of NESTORE were:

- The different stakeholders identified two very distinct markets with the higher potential for the successful commercialization of the NESTORE Virtual Coach.

The first one is a “medical” market and envisages the inclusion of the NESTORE Virtual Coach as one of the services provided by health authorities to the citizens. NESTORE would be included in the reimbursement schemes of the different national health services following, therefore, a Freemium model. This market would leverage institutional channels such as hospitals but also pharmacies and drug stores. Key partners in this ecosystem would be physicians, general practitioners and pharmacists, which are in close contact with the target users of NESTORE. As pointed out by several stakeholders, to access this market, it would be necessary for NESTORE to obtain a certification as a medical device requiring a thorough clinical trial for the developed solution.

The second market is one of the fitness digital devices and solutions to improve personal physical well-being. This market would involve a more varied ecosystem that includes stakeholders, partners and channels such as personal trainers and influencers, eCommerce, gyms and fitness centres, as well as consumer electronic stores and retailers. NESTORE would be sold directly to consumers (B2C scheme) following an out-of-pocket model. Some stakeholders have also indicated the possibility of adopting a subscription model like that of a gym (with monthly or annual renewals). Furthermore, to facilitate the integration with other fitness devices already used by potential customers, NESTORE should leverage an interoperable system. In this market, as suggested by different stakeholders, it would be also possible to target a younger segment of the population (i.e. 50 years and older) together with the designed target of the NESTORE solution.

- Several stakeholders reported the presence of very few solutions similar to the NESTORE virtual coach on the market; therefore, NESTORE could take the first-comer position gaining a relevant competitive advantage. However, it was also highlighted that several similar of both small companies (such as innovative start-ups) and big players are currently underway. Therefore, the time to market represents a key driver for the success of the MA strategy of NESTORE, raising the necessity to launch the virtual coach in the shorter time possible. In this sense, the fitness B2C market previously described would represent the most desirable market choice.
- Once the EC-funded period will be finished, NESTORE should look for an industrial player (especially in the pharmaceutical, biomedical or insurance sectors) or investment fund whose role will be to take over the project providing the necessary financial and commercial resources and leading to the successful launch on the market.

4.4 Step IV: market access strategy refinement and business plan

The last step of the E&D Canvas is the designing and fine-tuning of the MA strategy based on the insights gathered from the stakeholders involved. Subsequently, a detailed business plan for the MA strategy designed able to provide a holistic view of how this strategy could create, deliver and capture value should be developed. The business plan should include a thorough analysis of the market and external environment applying several dedicated tools (such as the political, economic, social & technological analysis, Porter’s Five Forces and the competitors matrix), a study of the distinctive

capabilities and resources that can make the company succeed in the market, the definition of the business strategy and model (value proposition canvas and business model canvas), the design of the most suitable marketing, operation, and a financial plan to prove the feasibility, sustainability and profitability of the designed MA strategy.

5. Discussion and conclusions

This study aims at furthering the ongoing debate about the MA of innovations in the health-care market with a particular focus on the exploitable outputs generated within EC-funded research projects. The still open challenge is matching the technological novelties with the needs of either the target users or the most relevant stakeholders – the so-called “market-product fit”.

Past contributions from scholars of industrial marketing proposed theories and frameworks taken from other industries. Despite their undoubted relevance, their generalizability to the health-care market is questionable and further research is needed (Schiaivone and Simoni, 2019). Past studies pointed out the urgent need for comprehensive MA approaches and competencies to facilitate the translation of innovations from labs to practice. However, extant research lacks relevant examples and case studies describing how an effective MA strategy should be organized in practice. This study sheds first light on this research context reporting the experience matured within the EC-funded project “NESTORE”. In this project, a novel framework for the MA of innovation in health care has been developed drawing on the principles of E&D set by the EC (European IPR HelpDesk, 2016).

The method is based on four sequential steps:

The first step covers the analysis of the external landscape including both the demand and the supply side. Regarding the former, the demand side should include desk analysis and the voice of the potential user (Bettiga et al., 2020). The desk analysis helps to understand the specificities of the different countries and their priorities, while empiric research involving potential users (implementing tools such as structured surveys) should be used to discover the determinants of their intention to use the designed solutions (Bettiga et al., 2020). Since the supply-side is frequently wide and borderless, the authors suggest that an effective analysis in the digital health and well-being market should investigate different domains:

- products and/or services that are – or will be if still under development – enough similar to the project solution and might be perceived by the potential users as comparable or substitute;
- start-ups able to collect institutional funds to develop products or services for the referred market; and
- other projects which are answering similar needs or developing similar solutions that may enter the industry soon.

The second step is about the definition of the MA strategy, i.e. the most suitable business model to bring the designed solution to the market and generate the expected impact. In this phase, different alternative MA strategies can be designed. The identification of the MA strategies should be informed by both internal and external analysis and should be crafted according to two main directions of diversification: for the NESTORE

project these were the level of integration and the type of revenue stream.

The third step deals with the involvement of the most relevant groups of stakeholders in the definition and validation of the most appropriate MA strategy. This step represents the core part of the D&E Canvas: the market validation is a fundamental phase to the development of any new and innovative business necessary to lead to a full understanding of a set of several diversified stakeholders usually involved in innovative projects (Kannan-Narasimhan and Lawrence, 2018). In line with the recent literature (Leone et al., 2021), a comprehensive mapping of the stakeholder involved in the innovation and decision-making processes allows complementing the information needed to achieve an effective MA strategy by understanding from the very first beginning their needs and expected outcomes. The major stakeholders are indeed involved not only to validate the MA hypothesis but also to define the right direction for the MA strategy according to their vision and point of view, eventually engaging them in a recurring conversation. According to the literature, we propose six main types of stakeholders that could be intended as a robust and valuable tool to support the identification of those groups of stakeholders that should be targeted in similar projects carried out in the health-care sector.

The fourth and final step should include the refinement and fine-tuning of the MA strategy and the development of a comprehensive business model to support the designed strategy.

This model has been developed starting from the major challenges, issues and needs regarding MA in health care emerging from the analysis of the literature. Particularly, we set a framework going beyond traditional marketing approaches (Schiavone and Simoni, 2019; Wenzel et al., 2014) and representing a continuative and integrated approach along with the different phases of the new product development (Guercini et al., 2020). Furthermore, the model has been integrated with a solid and evidence-based study of the market and of the context where the innovation will be introduced.

The proposed framework has also been developed in response to the common challenges hampering the capitalization of innovation in EC-funded projects such as big organizational variety, lack of defined decision-making hierarchy, missing a clear and unique direction for the innovation and great length of the project duration (Veugelers et al., 2015). For this reason, the scientific coordinators and Consortia behind other EC-funded projects could benefit from this framework to set a comprehensive and integrated MA strategy to maximize the research impact. By managing effectively E&D activities, they can facilitate the innovation potential to be turned into tangible solutions. This is especially important since, despite the efforts of the EC, there is still some confusion about how this activity should be addressed in the EC-funded research (European IPR Helpdesk, 2016). Contrary to traditional frameworks commonly used for implementing E&D activities in EC-funded projects (Kaur and Nikander, 2017), which favour and include in the strategy development only the view of the end-user (Sørensen et al., 2010), the novel framework established an inter-functional approach that combining E&D aimed at accessing and engaging a plurality of diverse stakeholders directly or indirectly

impacted by the innovation (Guercini et al., 2020; Koçkaya and Wertheimer, 2018; Thomas et al., 2018). In line with the most recent MA literature (Leone et al., 2021), end-users are just one of the types of stakeholders gravitating in the health-care ecosystem that should be involved in value creation and to effectively design and put in practice an MA strategy. Moreover, the steps proposed in this work can overlap to an extent allowing to iterate through the phases as needed. The flexibility of the framework goes beyond the classical process models traditionally used in more technology-centric projects where each phase should be done only once (Kaur and Nikander, 2017).

Some examples may clarify the potential benefits for the different groups of stakeholders. Firstly, principal investigators and project managers of EC-funded research projects are used to organize dissemination and exploitation as isolated activities. This *modus operandi* generates either redundant or conflicting strategies. Dissemination activities are often unfocused and try to reach the largest number of stakeholders without a shared understanding of why they should be involved. The D&E Canvas supports the identification of the most relevant groups of stakeholders and the rationale that grounds this choice. This allows to channel the time and resources of the Consortium in the most promising direction and to increase the probability of success of the exploitable outputs. Secondly, engaging with those groups of stakeholders which have been identified as the most relevant can facilitate the agreement on which innovative solutions should be prioritized in the exploitation strategy. Within the NESTORE research project, 20+ individual innovative outputs have been identified as potentially exploitable (Table 3).

The prioritization of these innovations is a complex task because it is the result of either a rational or a political process that must match the strategies of the Consortium as a whole with the strategy of the single partner of the Consortium. The voice of the most relevant stakeholders might inform this process of prioritization allowing the Consortium to take that choice that has the highest probability of commercial success. Thirdly, the project officer and reviewers might take advantage of the D&E Canvas to provide the Consortium with more contextualized feedback that is based on the strategies that have been set up to align dissemination and exploitation to get an appropriate “market-product” fit. Additionally, they might suggest potential groups of stakeholders to be involved to facilitate the MA of the most promising exploitable outputs. Fifthly, each group of relevant stakeholders that will be involved through a focused dissemination strategy might get a more comprehensive understanding of the rationale of their involvement and the potential linkages with other groups of stakeholders (Lamberti and Lettieri, 2009).

The findings of this study should be interpreted considering some limitations. Firstly, the research design is inductive and based on a single case. Future research should test the proposed framework on different projects also external to the EC-funded research model to better argue about the generalizability of our findings. Secondly, the innovations developed within the NESTORE project are still to enter the market and we did not have the opportunity to verify their actual success or unsuccess. In this view, further research should design a longitudinal study able to gather data

Table 3 NESTORE exploitable outputs classified by typology

Products	
Ex.O. 3 Sheffield	Design prototype
Ex.O. 1 TUD	Mobile digital game
Ex.O. 2 Zurich	Serious game for cognition
Ex.O. 2 FSIE	Gender Checklist
Ex.O. 1 LU-CIM	Use Habits Recognition Module
Ex.O. 2 LU-CIM	NESTORE EMOTIVE Wellbeing Engine
Ex.O. 1 NEOS	Sensor patient monitoring architecture
Ex.O. 3 HES-SO	Tangible coach
Ex.O. 1 Flex	Wearable device – smart bracelet
Ex.O. 2 Flex	Charging station
Services	
Ex.O. 2 EURECAT	Decision support system
Ex.O. 1 HES-SO	Conversational agent
Processes	
Ex.O. 1 Sheffield	Co-design methods
Ex.O. 1 HES-SO	Design guidelines
Know-how	
Ex.O. 3 Flex	Algorithm
Ex.O. 1 CNR	Descriptive models for healthy ageing
Ex.O. 2 CNR	Coaching plans
Ex.O. 3 CNR	The NESTORE specific ontology
Ex.O. 1 Zurich	Evidence-based intervention program
Ex.O. 1 FSIE	Steps for interaction system-individual
Ex.O. 2 HES-SO	Implementation of behaviour change

over time about the adoption and diffusion phases to better argue about the capability of our method to provide clear practical guidelines about how to design and implement an effective MA strategy in the health-care context.

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