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The macro-level determinants of user entrepreneurship in healthcare: an explorative cross-country analysis

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Abstract

Purpose – This article analyses the new venture creation by patient innovators in 40 countries examining the effects of the four macro-level factors on entrepreneurship, adding a fifth sector-specific (healthcare) factor.

Design/methodology/approach – By applying the statistical tool of principal component analysis, we find a clustering behavior of health user entrepreneurs across countries, indicating that common macro-level conditions affect this phenomenon in a nonlinear way.

Findings – Healthy user innovators are more likely to become entrepreneurs in those countries where creativity, economic opportunities and business environment are increasing from the lower level until a certain threshold. After that level, user entrepreneurship seems to be not relevant.

Originality/value – We contribute to the extant literature about macro-level determinants of entrepreneurship by exploring how much such conditions impact on the decision to create new firm by user innovators.

Keywords User entrepreneurship, Healthcare, Principal component analysis

Paper type Research paper

1. Introduction

The impact of macro-level (country) conditions, such as culture or governance, on new business creation is well-known in entrepreneurship literature since a long time ago (Schumpeter, 1934; Hayton *et al.*, 2002; Wennekers *et al.*, 2002). An extensive body of research reports national conditions largely impact on the entrepreneurial intentions and activities of local people (Freytag and Thurik, 2007; Valdez and Richardson, 2013; Arin *et al.*, 2015). Over the last few years some empirical studies narrowed the focus of such research domain by analyzing the impact of macro-level (country) conditions on specific subsets of entrepreneurship (Thai and Turkina, 2014; Griffiths *et al.*, 2013; Hoogendoorn, 2016). The key goal of such empirical studies was to investigate if certain country variables can predict and determine, to some extent, the orientation and interest of country inhabitants toward a given form of entrepreneurial activity, such as informal entrepreneurship or social entrepreneurship.

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An emerging form of entrepreneurship receiving a growing interest by scholars is user entrepreneurship (Shah and Tripsas, 2007, 2016; Haefliger *et al.*, 2010; Schiavone *et al.*, 2019). Such novel form of entrepreneurship is the result of the entrepreneurial journeys by user innovators, users of an existing product or services that, at a given point, decide to innovate. User entrepreneurs usually form a viable and consolidated portion of new business' founders (Shah *et al.*, 2012). Most of the studies about this phenomenon focused on the micro (individual) determinants of the phenomenon (Block *et al.*, 2016; Hamdi-Kidar and Vellera, 2018). The large variations between the national rates of user innovation across countries (Franke *et al.*, 2016) suggest macro-level conditions are likely to play a role in supporting (or hampering) this type of new firms' creators.

Healthcare is one of the main industrial domains in which user entrepreneurship takes place all around the world (Von Hippel, 2017; Schiavone, 2020). However, to date, scholars have not provided any specific empirical investigation about the role played by the national context for user entrepreneurs in the healthcare sector. Such level of analysis and industrial domain should receive more attention by researchers and practitioners for two key reasons: first, understanding how national conditions impact on health user entrepreneurship and how it would be complementary to the already known differences across countries about the national rates of user innovation in the health and medical domains (Von Hippel, 2017); second, the small portion of healthcare consumers (less than 10%) becoming entrepreneurs in this sector (Demonaco *et al.*, 2020) generate an important waste of potential value that could be gained by all the industry actors.

Given these motivations, the present study aims at contributing to (1) the extant literature about macro-level determinants of entrepreneurship (Hoogendoorn, 2016; Thai and Turkina, 2014; Valdez and Richardson, 2013) and (2) the rising body of knowledge about user entrepreneurship in healthcare (Demonaco *et al.*, 2020; Schiavone *et al.*, 2020). The research question of the present article, thus, is: what are the macro-level conditions supporting the national level of user entrepreneurship in healthcare? We developed five hypotheses and tested them analyzing new venture creation by patient innovators in 40 countries. We explored the effects of three dimensions used in Thai and Turkina (2014), adding two more sector-specific (healthcare and natural environment) factors. Principal component analysis (PCA), nonlinear regression and cluster analysis were applied as main statistical methods. Our results show a clustering behavior of health user entrepreneurs across countries, indicating that common macro-level conditions affect this phenomenon in a nonlinear way. This implies health user innovators are less likely to become entrepreneurs in those countries where economic opportunities, such as business environment and the economic quality, people's resources and abilities, such as education quality and creativity, governance quality, the environment and the health attention are increasing from the lower level until a certain threshold. After that threshold, the rate of health entrepreneurs becomes more relevant. Various implications for policymakers, entrepreneurs and managers emerge from the results.

2. Literature review

2.1 Macro-level determinants of entrepreneurship

Literature in economics, management and entrepreneurship studies report a quite exhaustive list of country-level determinants of entrepreneurship for a while now (Arin *et al.*, 2015; Castaño *et al.*, 2015; Cuervo, 2005; Freytag and Thurik, 2007). These determinants can be technological, demographic, economic, cultural and institutional (Wennekers *et al.*, 2002). Arin and co-authors (2015) suggest the level of entrepreneurial activity in a country depends on the interplay between human capital, level of development and institutions. The availability of resources and competition are other critical environmental characteristics to consider in order to understand the entrepreneurial activity within a country (Cuervo, 2005).

The extent of both latent entrepreneurship and actual entrepreneurship in OECD countries can be explained by both country-specific (cultural and macro-economic) factors and economic factors (Freytag and Thurik, 2007). However, the impact of the various (social, cultural and economic) determinants is not homogeneous worldwide and changes across continents (Castaño *et al.*, 2015).

Various recent cross-cultural studies applied institutional theory (Scott, 1995) to analyze the impacts of macro-determinants on entrepreneurship across countries. Such theory assumes three pillars are relevant to achieve conformity and order within a social group (Scott, 1995): cultural-cognitive, regulative and normative. Valdez and Richardson (2013) in their institutional analysis of the Global Entrepreneurship Monitor (GEM) during the period 2005–2007 found some institutional conditions, namely culture and norms, and concluded that they are important antecedents of new business creation in a nation. These results are confirmed in both the opportunity- and necessity-motivated entrepreneurship. In line with these findings, Hechavarría (2016) provides further evidence that proves that culture matters in understanding the profile of national entrepreneurship by analyzing the 2009 GEM data from 53 countries. The author finds that traditional societal values positively impact commercial entrepreneurship prevalence rates but negatively impact social entrepreneurship rates. This finding stresses the critical role of national culture in promoting (or inhibiting) the entrepreneurial activity of local people (Hayton *et al.*, 2002).

Over the last few years, various empirical studies analyzed the macro-level determinants of specific domains of entrepreneurship. Among all, social entrepreneurship is probably the most investigated domain. This is a challenging and interesting domain for scholars since several macro determinants found to be relevant in commercial entrepreneurship do not play a role for the creation of new social companies (Griffiths *et al.*, 2013). For instance, a recent analysis on 2009 GEM data from 49 countries reports that public sector expenditures is the most important driver to increase the share of social entrepreneurial entry (Hoogendoorn, 2016). The same study also reports, in line with the findings by Hechavarría (2016), that self-expression societal values, such as social toleration, life satisfaction, public expression and an aspiration to liberty, positively impact on the rate of new social entry.

Macro-level determinants of entrepreneurship were not analysed just to explain the rise of social ventures. Thai and Turkina (2014) offer a detailed and exhaustive analysis about the impact of more macro-level determinants on different types of entrepreneurship. The authors via their model grounded on the eclectic theory of entrepreneurship (Verheul *et al.*, 2002) test four key macro-level determinants of formal and informal entrepreneurship in 52 countries: demand-side factors (economic opportunities), supply-side factors (resources and abilities), culture and quality of governance. The results show that the same factors can have very different impacts on formal and informal entrepreneurship. On one side, the quality of governance and economic opportunities support the rise of formal entrepreneurship. On the other side, socially supportive culture and low stages of development of the national economy are relevant drivers of informal entrepreneurship. In sum, prior research outlines how country-level determinants exert heterogeneous impacts on entrepreneurship in a country depending on the nature and mission of the new ventures under investigation.

2.2 User entrepreneurship

User entrepreneurs "create and commercialize innovative products in response to their own needs" (Oo *et al.*, 2019; Shah and Tripsas, 2007). The phenomenon of user entrepreneurship, thus, diverges from the standard entrepreneurial journey (Shah and Tripsas, 2016) since new business creators are user innovators (Von Hippel, 2017) commercially exploiting their situated knowledge about a specific problem they face daily. Agarwal and Shah (2014) developed a number of propositions about user-founded firms. These companies, which

primarily (1) introduce product innovations in the market are likely (2) to face critical entry barriers in the access to complementary assets and in the appropriability regimes, (3) to enter in niche or unserved markets in mature stages and, finally, (4) to create value mainly by establishing alliances and strategic partnerships.

User entrepreneurship occurs largely in several industries and is implemented by both end users and professional users (individuals or incumbent organisations). New firms launched by user innovators were around 12% of all the 2004 start-ups in the US (Shah *et al.*, 2012). The 84% of new firms founded between 1980 and 2007 in the juvenile products industry (firms producing products for infants and toddlers) were founded by end users such as fathers, mothers and grandparents (Shah and Tripsas, 2016). Professional users, instead, gain experience and perceive needs in their working environment. Sometimes professional users (established companies) use vertical diversification in order to create new firms and commercialise innovation (Block *et al.*, 2016). Medical industry is also rich of evidences about professional users (physicians) that, in a given point, decide to launch their new own businesses (Chatterji, 2009).

Literature widely analyzed at micro-level exposes the conditions that promote user entrepreneurship. Shah and Tripsas (2007) argue this kind of entrepreneurship takes place when users enjoy the initial production of the innovation, there are low opportunity costs and the industry is rich of small market niches. They also suggest that a user innovator is likely to start up a new firm if the expected profits from the commercialisation of the innovation are higher than the user's profits threshold to initiate the entrepreneurial process (Shah and Tripsas, 2016). Three significant factors leading consumers to become entrepreneurs are: (1) intrinsic motivations (e.g. enjoyment and the willingness to help other people). These type of motivations matter more than the ambition to gain profits or search for recognition (extrinsic motivations); (2) the lack of alternatives for users to promote the diffusion of their innovations in the market; finally (3) the lack of risks and negative impacts of the entrepreneurial journey on the normal professional activity of users (Hamdi-Kidar and Vellera, 2018). Referring to user firms, prior research shows lead userness is also positively associated to entrepreneurship (Block *et al.*, 2016).

Over the last years another important driver for user entrepreneurship was the wide spread of digital technology. Many established global companies, such as Dropbox (founded by an IT user frustrated of using a thumb drive with critical files) and Yahoo! (created by two PhD candidates in electrical engineering interested in Internet), were generated via this form of entrepreneurship (Shah and Tripsas, 2007; Oo *et al.*, 2019). The link between technology and this type of entrepreneurship was recognised by prior research showing that high-tech and R&D-intensive industries are its most common industrial setting (Shah *et al.*, 2012). The current rise of various technology-driven business phenomena (such as crowdfunding) stresses the centrality of user entrepreneurship for scholars, practitioners and policymakers. For instance, crowdfunding platforms are technological infrastructures supporting widespread occurrence of user entrepreneurs by providing easier access to market and capitals (Brem *et al.*, 2017). The rapid emergence of the so-called "maker movement", which is driven by the implementation of 3D printers and other digital technologies offers important implications for entrepreneurship research (Browder *et al.*, 2019).

2.3 User entrepreneurship in healthcare: some hypotheses about its macro-level determinants

Innovation in healthcare takes place via the interaction of a wide amount of stakeholders with heterogeneous goals: institutions willing to provide the best care services possible, firms willing to gain competitive advantages and profits, patients interested in contrasting their illnesses and the whole society aiming to improve as much as possible the national standards

of public health (Schiavone, 2020). Therefore, medical innovation needs to be an "interactive process involving a broad set of disciplines, agencies and institutions with closer relations emerging between firms, clinicians and academic scientists" (Consoli and Mina, 2009). Such assumptions make user innovation and user entrepreneurship in this industry complex processes, which need to be implemented via the tangible and intangible support of external partners (Schiavone *et al.*, 2020). An interesting evidence of user entrepreneurship in healthcare comes from patient innovation and consumers of healthcare services (Demonaco *et al.*, 2020). This concept refers to the situation by which "patients or their nonprofessional caregivers (e.g. parents, family members, spouses or partners) modify or develop a treatment, behavioural strategy, technical aid or a medical device to cope with their ailment" (Habicht *et al.*, 2013). Very often, patient innovations lead to the creation of new firms, very often based on digital technologies and aimed at exploiting the specific skills and experience of their founders (Schiavone, 2020).

Prior research scarcely analyzed the macro-level (national) determinants fostering user entrepreneurship in healthcare. Anyway, literature about user entrepreneurship provides some general inputs (very often recommendations for policymakers) stressing the great impact of national conditions on the likelihood of user innovators to become entrepreneurs. For instance, Holzmann *et al.* (2017) suggest in the 3D printing industry that low bureaucratic barriers and education can support this phenomenon within one country. National regulations about patents and intellectual property also play an important role in spreading user entrepreneurship (Haefliger *et al.*, 2010; Shah and Tripsas, 2016). Another important macro-level condition promoting the start-up of an entrepreneurial journey by user innovators should be social capital and presence of strong innovation communities, as reported in the cases of two Korean companies founded by users (Yun and Park, 2016).

Given these premises, by drawing mainly on the work by Thai and Turkina (2014) and key literature about user innovation and user entrepreneurship, we developed various hypotheses about the macro-level (national) determinants promoting this fascinating form of entrepreneurship in healthcare and will be further explained in the following paragraphs. Prior studies show that specific domains of entrepreneurial activities are expected to receive unpredictable, deep and heterogeneous impacts from these determinants such as the national culture, economic opportunities, resources and abilities and the quality of governance (Hechavarría, 2016; Thai and Turkina, 2014). Similarly, also prior research about user innovation indirectly reports countries with different resources, economic and governance characteristics also present different rates of the phenomenon. Probably, the greatest evidence of such cross-national differences is the large gap between the frequencies of user innovation in Sweden (approximately 27% on the total of innovation activities) and Korea (at least 6%) (Franke *et al.*, 2016).

In line with the findings by Shah and Tripsas (2007, 2016), all the demand factors (economic opportunities) and supply factors (resources and abilities) able to (1) decrease the entry barriers and opportunity costs for new entrepreneurs and (2) make easier profitability and the access to markets should be drivers of user entrepreneurship. For instance, among the various supply-factors reported by Thai and Turkina (2014), the distribution of prosperity could be relevant in order to make easier the emergence of market niches within an industry. The presence of many market niches (Agarwal and Shah, 2014), coming from the fact more people in a country can buy different products or services thanks to national prosperity, should encourage user innovators about the future profitability of their potential new companies. Referring to demand factors, the availability and spread of technological infrastructures should be a factor boosting user entrepreneurship, especially for those new ventures operating in digital domains or looking for customers or capitals mainly via digital platforms, as found in the cases reported by Brem *et al.* (2017). Drawing on these assumptions, we can develop the following hypotheses:

H1. The more a country offers economic opportunities, the more national user entrepreneurship in healthcare increases

H2. The more a country holds resources and abilities, the more national user entrepreneurship in healthcare increases

Also, the quality of national governance is likely to greatly affect the willingness of user innovators to become entrepreneurs. The well-working of public administrations and a slim bureaucracy, for instance, should decrease the opportunity costs for user innovators and, thus, also affect positively the likelihood of new business creation (Shah and Tripsas, 2007). Indeed, user innovators from countries with acceptable mechanisms of governance should find stronger incentives in business creation. Rival speculations could be developed about national programs for R&D. On one side, user innovators in countries where national governments promote R&D extensively could find easier to find resources for starting-up their new venture. On the other side, the lack of incentives from the government could oblige, to some extent, user innovators to create their own companies because they should be aware about both a) the difficulty to find local firms selling specific products or services for their personal needs b) the presence of an unserved domestic market. This argument is consistent with some of the findings reported by Hamdi-Kidar and Vellera (2018). Thus, we can propose the following hypothesis:

H3. The more a country has a good quality of governance, the more national user-entrepreneurship in healthcare increases

In the present article, we decided to not consider national culture, the fourth macro-level determinant used by Thai and Turkina (2014), as a stand-alone variable because we do believe various important culture-based elements were already present in the "supply factors" dimension (e.g. community and family networks, social tolerance). Instead, we consider other two industry-related variables. The first variable is the natural environment, which relates to the physical environment in which people live and, overall, greatly impacts on their present and future health conditions (Legatum Institute, 2018). Given this assumption, in a country with a low-polluted natural environment, the creation of a new venture should be easier for user innovators. Indeed, they should find more easily potential future stakeholders (customers, policymakers, industrial partners and so on) aware about the value and centrality of healthcare issues and willing to contribute actively to the preservation of good national levels of public health. Second, we suppose the attention to health within one specific country increases the social reputation and prestige achievable by user innovators and, thus, can push them to become entrepreneurs in this sector. Thus, we can propose the following two hypotheses:

H4. The more a country has a good natural environment, the more national user entrepreneurship in healthcare increases

H5. The more a country pays attention to health, the more national user entrepreneurship in healthcare increases

3. Sample data and method

3.1 Sample and measures

Data sample covered 359 innovations, created by patients or caregivers, 239 of them (67%) became entrepreneurial activities, across 40 countries and over the period 2014–2018. Data about health user innovations were obtained by means of a content analysis performed on Google, randomly selecting the innovation by searching for some disease keywords, about more than nine pathologies, such as: diabetes (4%), eye disease (7%), cancer (14%), ear

disease (5%), heart disease (4%), mental problem (8%), motor disability (31%), neurodegenerative disease (9%) and other diseases (17%).

3.2 Dependent variable

To measure the country-level health user entrepreneurship a variable ad hoc was created as a ratio between the "new business creations" related to patient/caregivers innovations and the total early-stage entrepreneurial activity (TEA) per country. "New business creations" denotes the health user innovations which a new startup ventures.

TEA, as count of adult population (18–64 years old) who are either a nascent entrepreneur or owner-manager of a new business, was drawn from GEM 2014. GEM was adopted considering the representativeness of the weighted sample of 200.000 adults interviews in each country under study.

3.3 Explanatory variables

To explore country-key factors of health user entrepreneurship, several reliable sources were selected to collect variables at country level, partially following the eclectic proposal of Verheul *et al.* (2002). Table 1 summarizes the variables involved in the analysis. In the macro perspective, the authors identified environmental factors, such as technological, economic and cultural variables as determinant of the level of entrepreneurship in a given country. The first distinction is between the supply side and the demand side factors. On the demand side, entrepreneurial opportunities are created by industrial structure and diversity of demand, both of which are determined by economic development, technological development and international economic integration. On the supply side, the entrepreneurship is determined by the characteristics of the population, such as the right resources, abilities and attitudes toward entrepreneurship. The cultural and institutional environment can influence the supply side of entrepreneurship. Education, social capital and environment were added to measure the prosperity of the country as possible facilitators of user entrepreneurship. The analysis focused on healthcare for two main reasons: first, this industry is one of the main household sectors in which user innovation takes place (Von Hippel, 2017); second, healthcare is an industrial domain in which user entrepreneurship is a frequent phenomenon, with relevant social and policy implications (Schiavone, 2020). Thus, variables related to healthcare were included in the study (e.g. contribution of health expenditure of GDP, basic health outcomes, infrastructure and preventative care, as reported in Table 1).

Table 1 summarizes variables encompassing both demand and supply side factors also related to Legatum Prosperity Index pillars (2018) which are: economic, business environment, personal freedom, safety and security, governance, education, social capital and health pillars. The natural environment and governance pillars have been considered alone, as two separated dimensions. Although all these measures are combined and enclosed into a prosperity index by Legatum Institute, this study separately involves each pillar as a component of prosperity to weigh each dimension in determining user entrepreneurship in healthcare.

However, the creativity and the innovation level of the country were also considered as possible determinants of user entrepreneurship and then, respectively, included in demand-side and supply-side country factors. The health expenditure (% GDP) was included as health attention dimension given its importance in the conceptual framework.

Specific national context dimensions were included as controls both in demand- and supply-side factors, e.g. the contribution of research and development to GDP, GDP per capita, the contribution of researchers and technicians to total population.

Finally, merging different datasets, the sample size was reduced to 33 countries, due to lack of information of some main dimensions.

Categories	Cross-country data	Sources of data	Data year
Demand factors (economic opportunities)	(1) Structural policies	Legatum Prosperity Index: Economic Quality pillar	2018
	(2) Economic satisfaction and expectations	Legatum Prosperity Index: Business Environment pillar	2018
	(3) Distribution of prosperity	World Economic Forum	2018
	(4) Engagement	World Bank	2018
	(5) Production quality and diversity		
	(6) Long-run per capita income growth		
	(7) Access to infrastructure (Internet, transport and to credit)		
	(8) Business flexibility		
	(9) Clear and fair regulation and perceptions of meritocracy and opportunity		
	(10) Innovation		
	(11) Contribution of R&D to total GDP		
Supply factors (resources and abilities)	(1) National security	Legatum Prosperity Index Safety and Security Pillar	2018
	(2) Personal precariousness	World Bank	2018
	(3) Personal safety	Legatum Prosperity Index	2018
	(4) GDP per capita	Personal freedom Pillar	2018
	(5) Basic legal rights	Legatum Prosperity Index Social Pillar	
	(6) Individual freedom		
	(7) Social tolerance		
	(8) Social cohesion and engagement	Legatum Prosperity Index	2018
	(9) Community and family networks	Education Pillar	2015
	(10) Political participation and institutional trust	Martin Prosperity Institute	
	(11) Access to education	World Bank	2018
	(12) Quality of education		
	(13) Human capital		
	(14) Creativity		
	(15) Contribution of Researchers and technicians to total population		
Quality of governance	(1) Effective and accountable government	Legatum Prosperity Index Governance Pillar	2018
	(2) Fair elections and political participation		
	(3) Rule of law		
	(4) Level of a country's democracy		
Environment	(1) Natural Environment	Legatum Prosperity Index Natural Environment Pillar	2018
Health	(1) Contribution of health expenditure to total GDP	World Bank	2018
	(2) Basic health outcomes	Legatum Prosperity Index Health Pillar	2018
	(3) Health infrastructure and preventative care	Google disease search keywords	2018
	(4) Physical and mental health		
	(5) New business creation in health-care sector		

Table 1. Determinant of entrepreneurship across countries

3.4 Research method

In order to verify the research hypotheses about the country-key macro-level conditions contributing to develop user entrepreneurship in health sector within countries and since the determinants of entrepreneurship can be studied from different perspectives, a quantitative analysis of dependence was considered a suitable research method.

To provide a better insight of the macro determinants of health user entrepreneurship and to try to developing some managerial and policy implications, the research methodology was organized in several phases: (1) the analysis of the relevant literature on the country factors driving the entrepreneurial activity to select variables in the analysis; (2) a sampling of primary data to evaluate the health user entrepreneurship; (3) an analysis of dependence to individuate the mechanism of influence within country factors on user entrepreneurship; (4) an exploratory analysis of clustering behavior in response to similar macro-level conditions as data driven approach to decision-making for entrepreneurs, managers and policymakers.

Factor analysis, nonlinear regression model and cluster analysis were adopted as main statistical tools. Such exploratory techniques aim to define the dependence structure of the model; conversely, other techniques, such as SEM models, often recurring in empirical analysis, require an a-priori theory approach, not suitable for an investigative research. They are most often used to determine the extent to which an already established theory about relationships among (explanatory) variables is supported by empirical data (Ockey, 2013).

A multiple regression model, attempting to explain the different health user entrepreneurship across countries, requires orthogonal regressors, and, then, independent explanatory variables, to avoid multicollinearity problems. Thus, an exploratory factor analysis (EFA) with the principal component method (Hotelling, 1933) was applied as data-driven approach. Generally adopted to identify the structure of relationships among variables, EFA technique can lead to a reduction of dataset dimension, obtaining from a set of original variables a smaller set of meaningful orthogonal "components". The strategy of this statistical tool, particularly suitable for dependence modeling, consists in simplifying the number of variables in dependence analysis, exploiting their correlations and removing the multicollinearity issue when they are involved as regressors in a regression framework.

Therefore, to assess the dependence model between user entrepreneurship and country macro determinants, a regression model was carried out. In order to extend the flexibility and thus applicability of this already useful statistical modeling method, a natural extension of linear dependence modeling is to include the chance of modeling nonlinear relations among the observed variables in addition to linear relations. Then, a nonlinear regression model was also considered to control for any possible nonlinear effects.

Finally, a cluster analysis (Grover and Vriens, 2006) was applied to identify possible agglomerations of countries sharing common characteristics in relation to the selected key factors. Cluster analysis is a recursive statistical technique that allows to split n-units into groups, in function of a divisive criterion which aims to maximize the internal homogeneity within the observed clusters. Such a statistical tool attempts to describe the common characteristics of each country group allowing for: (1) a better specification of the role that each variable plays within country group, (2) a wider discussion of the results and (3) a clearer understanding of managerial and policy implications.

To the best of our knowledge, this is the first contribution in literature that explores macro determinants of health user entrepreneurship by such a statistical methodology. The research method answers to the objective to explore all possible dependence structures among variables, also nonlinear, without imposing any *a priori* theory approach. Furthermore, a statistical description of common features of countries are also documented. All analyses were performed by means of the R and SPSS statistical software.

4. Results

Table 2 reports the linear Pearson's correlations among variables and the main descriptive statistics of variables included in the research. Table 3 shows Kendall's tau nonparametric correlations which allow to account any dependence relationships, also nonlinear.

Table 2.
Pearson correlations and descriptive statistics

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1. Health user entrepreneurship	1															
2. Health expenditure (% of GDP)	0.688**	1														
3. Innovation index	0.464**	0.586**	1													
4. Creativity index	0.395*	0.649**	0.705**	1												
5. GDP per capita	0.349*	0.452**	0.772**	0.788**	1											
6. R&D expenditure (%of POP)	0.316	0.510**	0.845**	0.555**	0.622**	1										
7. Researchers and technicians; (% of POP	−0.125	0.144	0.315	0.380*	0.398*	0.402*	1									
8. Natural environment	0.198	0.513**	0.275	0.720**	0.539**	0.172	0.386*	1								
9. Health pillar	0.22	0.428*	0.682**	0.753**	0.790**	0.676**	0.382*	0.487**	1							
10. Economic quality pillar	0.341	0.521**	0.837**	0.743**	0.777**	0.697**	0.343	0.479**	0.772**	1						
11. Education pillar	0.410*	0.543**	0.839**	0.826**	0.871**	0.749**	0.369*	0.500**	0.832**	0.866**	1					
12. Social pillar	0.326	0.606**	0.642**	0.816**	0.627**	0.380*	0.343	0.641**	0.514**	0.726**	0.685**	1				
13. Governance pillar	0.248	0.551**	0.790**	0.727**	0.720**	0.551**	0.350*	0.555**	0.600**	0.826**	0.756**	0.859**	1			
14. Safety and security pillar	0.125	0.453**	0.585**	0.727**	0.775**	0.537**	0.424*	0.628**	0.800**	0.745**	0.746**	0.571**	0.726**	1		
15. Business environment pillar	00,442*	0.571**	0.800**	0.703**	0.775**	0.562**	0.226	0.506**	0.633**	0.882**	0.823**	0.791**	0.892**	0.642**	1	
16. Personal freedom pillar	0.19	0.572**	0.413*	0.725**	0.441*	0.218	0.235	0.711**	0.461**	0.516**	0.509**	0.793**	0.742**	0.609**	0.576**	1
**$p < 0.01$,*$p < 0.05$																
Mean	3,211	8,330	4,239	0.688	67,521	75,989	68,134	68,008	55,033	61,262	72,146	61,025	70,741	34,621	1,609	3,789
St.dev	5,879	2,642	0.931	0.208	8,297	6,683	7,887	10,365	7,801	15,303	11,323	9,540	18,185	19,783	1,080	6,364

Table 3.
Kendall's tau correlations

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1. Health user entrepreneurship	1															
2. Health expenditure (% of GDP)	0.387**	1														
3. Innovation index	0.389**	0.431**	1													
4. Creativity index	0.334**	0.523**	0.491**	1												
5. GDP per capita	0.318**	0.471**	0.645**	0.664**	1											
6. R&D expenditure (% of POP)	0.378**	0.450**	0.705**	0.424**	0.587**	1										
7. Researchers and technicians (% of POP)	0.145	0.353**	0.392**	0.495**	0.544**	0.455**	1									
8. Natural environment	0.149	0.497**	0.285*	0.487**	0.427**	0.311*	0.432**	1								
9. Health pillar	0.202	0.377**	0.589**	0.586**	0.703**	0.569**	0.534**	0.398**	1							
10. Economic quality pilar	0.244*	0.397**	0.669**	0.590**	*0673**	0.554**	0.439**	0.424**	0.655**	1						
11. Education pillar	0.335**	0.401**	0.623**	0.646**	0.813**	0.546**	0.489**	0345**	0.652**	0.663**	1					
12. Social pillar	0.274*	0.441**	0.431**	0.650**	0.502**	0319**	0.383**	0.489**	0.409**	0.527**	0.523**	1				
13. Governance pillar	0.267*	0.481**	0.569**	0.601**	0.586**	0.433**	0.489**	0.473**	0.538**	0.678**	0.591**	0.667**	1			
14. Safety and security pillar	0.11	0.357**	0.439**	0.525**	0.612**	0.448**	0.545**	0.538**	0.564**	0.576**	0.534**	0.405**	0.527**	1		
15. Business environment pillar	0.312*	0.457**	0.585**	0.616**	0.624**	0.406**	0.405**	0.428**	0.523**	0.655**	0.621**	0.583**	0.720**	0.436**	1	
16. Personal freedom pillar	0175	0.469**	0.308*	0.571**	0.438**	0.231	0.417**	0.462**	0.398**	0.409**	0.451**	0.625**	0.572**	0.394**	0.458**	1

Note(s): **$p < 0.01$, *$p < 0.05$

The analysis of correlations, both linear and nonparametric, denotes high associations between the dependent variable, "new business creations from health care (% TEA)" and each explanatory variable, considered as possible country-key factors of health user entrepreneurship. Such feature made the multiple regression model suitable for the analysis. However, the high linear correlations among country-key factors (as reported in Table 2) suggest reducing the number of dimensions to work on to avoid the multicollinearity issue inherent in dependence modeling. An exploratory factor analysis (EFA) with principal component method was performed in all 15 independent variables. First, the identification of the latent construct of each group of variables (which are here considered as reflective indicators because highly correlated to each other) was based on the grouping scheme of Table 1.

The application of EFA gives three components (which account for 82% of the overall variance of the dataset, Table 4), and the first dimension was used for further elaborations. Therefore, three components measure the latent constructs related to economic opportunities, resources and abilities and quality of governance and health, and the high correlations among constructs (Table 4) suggest combining them in a single component.

Such first component is mainly related to what one could denominate innovation-driven wealth of the country, a multidimensional component built on the high positive correlations of this factor with some indicators and pillars of prosperity especially involved in the presence of *"economic opportunities"*, such as the economic quality pillar (0.908), the business environment pillar (0.882), the innovation (0.854), included in *"resources and abilities"* , such as safety and security (0.833), social (0.837) and education pillars (0.922), GDP per capita (0.873), creativity (0.905), in the *"quality of governance"*, and, in a lower measure, in the *"natural environment"* and in the *"attention to health"* , as the health pillar (0.825) and the contribution of health expenditure to GDP (0.671). Such indicators have also higher communalities. The innovation of a country is particularly associated to creativity, as expected, so the countries more creative are also more innovative ($r = 0.705$, Table 2).

The relevance of some of Kendall's tau coefficients (Table 3), where linear correlations are not significant (Table 2), e.g. between economic quality pillar and health user entrepreneurship, suggests to control for possible nonlinear effects by means of a curvilinear regression model, as suggested by the scatter plot of the variables highlighting

	Factor loadings		
	1	2	3
Education pillar	0.922	−0.225	−0.006
Economic quality pillar	0.908	−0.183	−0.094
Creativity index	0.905	0.171	0.055
Governance pillar	0.896	0.115	−0.161
Business environment pillar	0.882	−0.024	−0.275
GDP per capita	0.873	−0.185	0.121
Innovation index	0.854	−0.375	−0.229
Social pillar	0.837	0.352	−0.155
Safety and security pillar	0.833	0.026	0.273
Health pillar	0.825	−0.233	0.219
R&D expenditure (% of POP)	0.709	−0.566	−0.015
Personal freedom pillar	0.707	0.596	−0.064
Health expenditure (% of GDP)	0.671	0.19	−0.321
Natural environment	0.664	0.57	0.281
Researchers and technicians (% of POP)	0.445	−0.068	0.728
Variance (%)	*64,866*	*10,151*	*6,957*

Table 4.
Factor loadings

a quadratic relationship. The model was performed considering the health user entrepreneurship as dependent variable and the component related to the innovation-driven wealth as regressor, also using its squared values, to take into account a nonlinear dependence structure. Therefore, also using squared values of the regressor, an improving of fit emerges in modeling the joint behavior. Findings show a significant quadratic relationship. In particular, a *U*-shaped relationship between macro determinants and health user entrepreneurship is defined, as reported in Figure 1 ($F = 7.475$, $p = 0.002$). Such nonlinear dependence would imply that the innovation-driven wealth factor is a facilitator of user entrepreneurship in health starting from a given threshold after that the health user innovations and, then, the entrepreneurship tends to increase. In particular, after a given level of prosperity, well-being conditions and innovations are supported by creativity; the more the innovation-driven wealth is high across countries, the more health user entrepreneurship increases. All hypotheses, from 1 to 5, are then supported. Given the positive relationships between the innovation-driven wealth factor and the presence of economic opportunities, of resources and abilities, of quality of governance, of natural environment and of attention to health, the more a country offers high levels of these indicators, the more national user entrepreneurship in healthcare increases.

Looking at the configuration of the countries per health user entrepreneurship and innovation-driven wealth results in groups of countries characterized by an internal homogeneity. Then, the analysis attempts to explore the presence of a clustering behavior with respect to these two dimensions. For this purpose, a hierarchical cluster analysis applied to all the variables of dataset gives us four clusters (as shown in Figure 2). Then a *k*-mean cluster analysis was applied to give the final configuration. Figure 2 reports the graphical configuration of the resultingfour4 clusters with respect to the dependent variable, health user entrepreneurship, and to the first EFA component innovation-driven wealth. Table 5 reports the average values of each variable involved in the innovation- driven wealth component per cluster. The average values reveal that cluster 4, composed by countries reported in Figure 2, is one of the wealthy clusters (as showed by means of variables related to prosperity pillars in Table 5), where the innovations are probably generated in different sectors, not related to health and the health user entrepreneurship mean is very low (1.969, Table 5). Moreover, the high rate of researchers and technicians on the total population would suggest that the countries of the fourth cluster are not properly user innovators or/and new

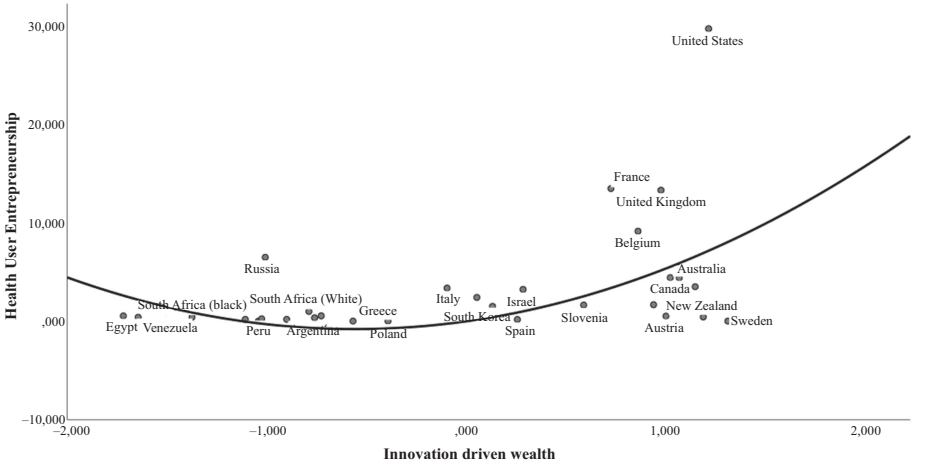

Figure 1.
U-shaped relationship between health user entrepreneurship and innovation-driven wealth

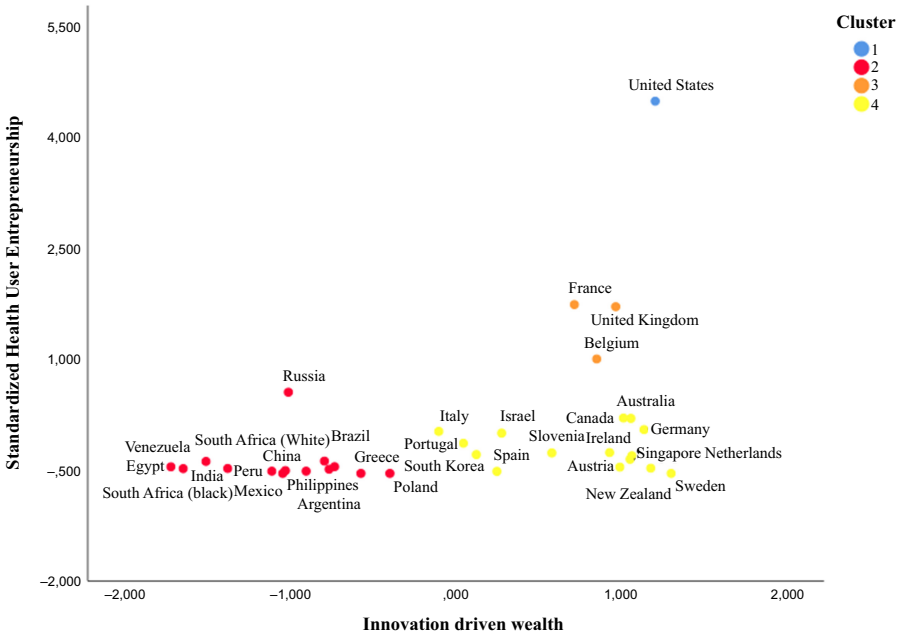

Figure 2.
Health user entrepreneurship and macro determinant–based clusters

business creators, but rather they are facilitated by the presence of "professional" innovators. As a matter of fact, the health user entrepreneurship is lowest, as well as in the cluster 2, which incorporates the poorer countries, where people are not in the conditions to develop user innovations and consequently user entrepreneurship.

Countries of clusters 1 and 3, standout, in particular cluster 1, which is formed uniquely by United States; it shows high values of health user entrepreneurship being in higher position with respect to wealth, prosperity, creativity and innovation. Differently from cluster 4, in these two clusters the general rate of health expenditure, for public as well as private health services, on GDP is very high. In addition, the presence of research and technicians is not relevant in cluster 4, confirming our previous hypothesis. Therefore, countries with a higher level of financial and economic well-being and prosperity could not drive to relevant rate of userentrepreneurs in health, maybe demanding to other sectors their creativity and inclination to innovation.

Such clustering behavior emphasizes findings related to curvilinear relationship suggesting that higher wealth conditions supported by innovation jointly with healthcare financing enable health user entrepreneurship to be developed, while lower levels of financial and economic well-being, upliftment and prosperity could not enhance the user entrepreneurship in the health sector.

To sum up, the analysis found out that three factors are representative of the overall variability of the dataset (more than 82%, Table 4). However, the first of these components denotes that innovation-driven wealth turned out to be a key determinant contributing to develop the health user entrepreneurship. High levels of this component are positively related to all demand factors (economic opportunities) and supply factors (resources and abilities), to a good quality of governance and of natural environment and to a high health attention. The analysis finds out a significant *U*-shaped relationship between user entrepreneurship in health sector and innovation-driven wealth. Higher levels of innovation-driven wealth per

Table 5.
Cluster means

Cluster	Health user Entrepreneurship	Health expenditure (% of GDP)	Innovation index	Creativity index	GDP per capita	R&D expenditure (% of POP)	Researchers and technicians (% of POP)	Natural environment	Health pillar	Economic quality pillar	Education pillar	Social pillar	Governance pillar	Safety and security pillar	Business environment pillar	Personal freedom pillar
1	29,581	17,000	5,800	0.950	59,500	2,790	0.130	68,543	78,289	75,765	78,914	65,452	68,366	71,105	75,872	77,852
2	0.793	6,430	3,371	0.490	16,386	0.713	0.383	62,483	69,783	60,955	57,989	48,573	47,464	61,967	53,014	57,739
3	11,917	10,670	5,000	0.840	44,500	2,130	2,409	74,813	81,096	74,556	77,402	58,134	73,157	78,979	68,684	84,871
4	1,969	9,070	4,793	0.826	48,007	2,263	7,488	70,697	80,608	73,041	74,754	59,749	71,287	80,350	65,980	79,575
Total	3,211	8,330	4,239	0.688	34,621	1,609	3,789	67,521	75,989	68,134	68,008	55,033	61,262	72,146	61,025	70,741

country match with higher level of health user entrepreneurship, making these country factors a driving force for user entrepreneurship, supporting and enhancing to start up a new venture. All five hypotheses are then confirmed.

A clustering behavior of the countries emerges from the analysis, four clusters of which United States is a single component of one cluster. Countries of the second cluster (in red, Figure 2) which innovate in health, as well as in other sectors (showing higher levels of patents and patents per capita, greater than median for all countries), e.g. Russia and South Korea, could increase their low user entrepreneurship enhancing the level of education, improving the quality of governance (in line with Thai and Turkina, 2014) and creating better conditions for business environment. The analysis of cluster variable means carries out other relevant determinants of user entrepreneurship in healthcare, the rate of health expenditure on GDP (positive impact) and researchers and technicians (negative impact) which resulted at the same time linearly related with health user entrepreneurship, in a stronger way, and also nonlinear related to innovation-driven wealth. The rate of health expenditure is indeed positively correlated to health user entrepreneurship, supporting again hypothesis 5 and stating that in countries where the innovation-driven wealth is low the high costs of public and private health services promote patient user innovations which then encounter significant difficulties to become start-up. While in countries with high values of innovation driven wealth the low cost of health services jointly to a high rate of researchers and technicians does not push the creativity of people to innovate in health and then to start up new venture, such as for instance in Sweden. In order to attain in-depth discussion of the results, the analysis would include other cultural variables (from Hofstede or Globe) to improve the curvilinear relationship fit and to better explain the country clustering behavior.

5. Discussion and implications

5.1 Theoretical contributions

The findings of our study contribute to several different but complementary bodies of knowledge. First, the article contributes to the theory about the country key characteristics supporting entrepreneurship (e.g. Arin *et al.*, 2015; Thai and Turkina, 2014). Our industry-based study adapted and extended the set of drivers originally developed by Verheul *et al.* (2002) and re-used by Thai and Turkina (2014) by considering additional sectorial variables (at national level) and selecting appropriate data sources for all investigated dimensions. Our findings provide clear evidence also about this additional type of variables, such as health attention, relevant in order to properly analyze the entrepreneurial phenomena. Moreover, the present study proposes and found the notion of innovation-driven wealth reliable, a more specific form of national wealth focused on the exploitation of innovation-related activities. Such a notion extends the set of usual variables, such as economic prosperity or GDP per capita; scholars in this stream of literature (e.g. Arin, 2015; Cuervo, 2005; Thai and Turkina, 2014; Wennekers *et al.*, 2002) usually considered in order to measure the demand factors affecting on entrepreneurship.

The indicator of innovation-driven wealth is more related to some aspects of prosperity, such as education, quality of economic and governance and the business and natural environment and to the creativity of countries. The study confirms that demand-side factors (economic opportunities), supply-side factors (resources and abilities), governance quality, natural environment and the attention to health within countries can have an impact on the health user entrepreneurship.

Our findings show a *U*-shaped relationship between the innovation-driven wealth and the health user entrepreneurship across countries, implying that increasing levels of the key-factor become more relevant for user entrepreneurship in healthcare.

A second contribution to the literature consists in confirming the positive relationships among economic opportunities, resources and abilities and quality of governance which promote health user entrepreneurship. The study validates the institutional economic literature for which the regulatory efficiency stimulates the economic development which in turn increases people's resources and abilities.

Therefore, the health attention within a country encourages the user innovations and then the related entrepreneurial activities, under economic well-being and upliftment conditions.

Third, our findings provide new knowledge about the theory of user entrepreneurship in the healthcare sector (Shah and Tripsas, 2016; Demonaco *et al.*, 2020; Schiavone *et al.*, 2020). Our study provided evidence that this phenomenon does not depend only on some micro-conditions, such as the user motivations, expected benefits or low entry barriers but also on innovation-related country-level factors, closely connected to the national wealth, making the entrepreneurial journey for the health user innovator more (or less) interesting and doable. Our study also extends the findings by Agarwal and Shah (2014) by suggesting that national macro-conditions augment (or minimize) the roots of some usual problems faced by user-founded companies. In countries, for instance, with inefficient governance, low economic prosperity or poor infrastructure the lack, for instance, of complementary assets or profitable market niches (factors hampering user entrepreneurship) are more critical. Conversely, in countries with better macro-conditions, the national rate of health user entrepreneurs rises. This translates into the user innovators' greater predisposition to innovate where healthcare national conditions are worse, and the government does not provide the minimum support to improve health conditions. This feature is often joined with the difficulty to create new business.

Finally, the present study highlights a clustering behavior across countries in health user entrepreneurship in response to similar macro level conditions; such behavior can represent a data- driven approach to decision- making for entrepreneurs, managers and policymakers.

The present study also provides an interesting methodological contribution. Despite their simplicity, the statistical tools here adopted (principal component analysis, nonlinear regression and cluster analysis), are found to be valid tools for understanding how user entrepreneurship is influenced by various macro-level variables.

5.2 Implications for entrepreneurs and managers

The results of the study also offer some relevant implications for both potential entrepreneurs and managers. First, user innovators willing to start-up their own company need to acquire an in-depth knowledge about some macro-level characteristics of their country (e.g. quality of governance, wealth and orientation to innovation) and try to figure out in which cluster their nation is located. Such knowledge would help these individuals in assessing if country-level conditions would support (or hamper) the launch of their future entrepreneurial initiative. In other words, health user entrepreneurs must be conscious about the macro-level determinants of their own countries and exploit these determinants to facilitate the creation of new firms. Second, potential business creators from countries in which user entrepreneurship is not definitely spread could consider establishing collaborations at an international level or, more radically, to relocate and launch their firm elsewhere, in nations with macro-level conditions more favorable for this kind of entrepreneurial initiatives. Countries as USA or the nations within the first cluster, in which innovation-driven wealth is present, could be interesting options for entrepreneurial emigration.

This paper brings value also to the practice of entrepreneurship. First, health user entrepreneurs need to develop their own personal skills and capabilities in order to take as best as possible the advantages and resources offered by their national environments. Successful health user entrepreneurs, in order to achieve this goal, should be able to find

strategic synergies across countries and/or sectors. Second, health user entrepreneurship is the process of taking innovations to the health market and applying them widely within an health ecosystem. Health user entrepreneurs, especially if they come from countries less oriented to entrepreneurship, therefore need to contribute to the upgrade of their entire ecosystem and its main stakeholders (e.g. patients, institutions). To this end, their entrepreneurial initiatives should be driven by a long-term systemic goal and not limited to short-term financial interests (Bonfanti *et al.*, 2016). They have to aim at creating long-term value for their companies and health support for their community, in collaboration with other stakeholders.

Referring to management, managers of start-up firms launched by user entrepreneurs that are planning and crafting their strategy should preferably partner with interorganizational collaborations (e.g. joint ventures), companies localized in countries within better clusters or within local innovation systems. Indeed, these companies should hold the typical cultural traits and benefit of the most suitable macro conditions for the rise of user-founded companies. The availability of such assets could to some extent compensate the lack and weaknesses of their national macro environment.

5.3 Policy implications

Various implications for policymakers emerge from our research. First, countries with macro-level characteristics associated with low rates of user entrepreneurship in healthcare should improve and spread innovation-driven wealth, at least in those regions or metropolitan areas where the frequency of user innovators is higher. These public initiatives should also try to enhance all the processes related to governance and public bureaucracy. The creation of a national environment based on "innovation-driven wealth" for health user entrepreneurs is extremely important. This process should be implemented with the support of the finance industry (i.e. the government can offer loan guarantees to national banks for their lending to social entrepreneurs in order to offset the perceived risk).

Second, our findings suggest countries within the same cluster should adopt similar policies and co-operate to some extent in order to promote health user entrepreneurship. For instance, national governments willing to increase this type of new businesses could establish joint programs of entrepreneurial development in collaboration with other countries within the same cluster. These programs could be tailored on the cluster' specific issues (e.g. low level of innovation-driven wealth).

Finally, it could be beneficial to set up educational programs for potential health user entrepreneurs by which sharing basic knowledge and best practices from the most entrepreneurial countries on how to build a new business in healthcare.

5.4 Limitations and future research

This article does not come without limitations. First, the study only focuses on industry. Data from more industrial sectors could suggest different relationships among variables and, at the end, provide different findings. Second, the sector investigated in the present study (healthcare) is organised across countries in different ways. In some countries (as USA), healthcare is mainly private, while in other nations (such as many European nations) the system is publicly funded. Such element of divergence definitely impacts on how the sector works and, thus, could generate bias regarding any cross-national study about this industry. Third, another limitation of the present study was the lack of the national cultures within analysis, which definitely might add value and extend our findings.

We believe our findings can be sources of various further investigations. For instance, future research could focus on the performance reached by user-entrepreneurs from countries located in different clusters. A second interesting future research stemming from our study could analyze industries with different characteristics. For instance, user entrepreneurship in

less capital-intensive industries could follow (and be affected by) different macro determinants and processes.

Finally, countries should take the opportunity to investigate whether some other variables, besides the ones we found in this study, can predict and determine the orientation of inhabitants toward a structured and successful form of entrepreneurial activity, such as informal of social entrepreneurship.

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