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INNOVATION AND TECHNOLOGY TRANSFER OF MEDICAL DEVICES FOSTERED BY CROSS-DISCIPLINARY COMMUNITIES OF PRACTITIONERS

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Commercialisation of emerging technological innovations such as medical devices can be a time-consuming and lengthy process resulting in a market entrance failure. To tackle this general problem, major challenges are being analysed, principally focusing on the role of Communities of Practitioners (CoPs) in the process of effective transfer of high-value emerging technologies from academia to market. Taking a case study approach, this document describes the role of a cross-disciplinary CoP in the technology transfer process

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within a convergence scenario. The case presented is a sensor array for ischemia detection developed by different practitioners from diverse organisations: university, research institution, hospital, and a scientific park. The analysis also involves the innovation ecosystem where all stakeholders are taken into account. This study contributes to a better understanding of the managerial implications of CoP fostering technology transfer and innovation, principally focused on the current need for new biomedical technologies and tools.

Keywords: CoP; medical devices; innovation, technology transfer; ischemia.

Introduction

Managing and commercialising emerging technological innovations such as medical devices is difficult to achieve (Symmank *et al.*, 2015). It is well known that most of the scientific breakthroughs produced in academia fail to become a marketable product or process (Linton and Walsh, 2004, 2008). Most of the investigations into medical devices have paid close attention to their research, design and deployment but few are examined from the point of view of the technological transfer and commercialisation challenges. Additionally, there is a vast demand for availability of devices such as sensors and smart devices for monitoring and follow-up of patients. Consequently, the resulting scenario has been conceptualised as a *gap* (Rasmussen and Rice, 2012) or a *chasm* (Flynn and Wei, 2005) between academic research and market. Associated with this problem are the asymmetric information transferred and the high production costs (Fu *et al.*, 2011; Motyl and Filippi, 2014; Siegel *et al.*, 2003).

CoPs are social organisational forms, considered vehicles for creating value in organisations because they effectively materialise innovation products or services (Lesser and Storck, 2001). The concept of CoP was originally introduced by Lave and Wenger (1991) and further analysed by Wenger (1998) who associated a communitarian approach with a “legitimate peripheral participation”. Since then, an exponential growth in the literature with applications in multiple areas has emerged (Amin and Roberts, 2008; Hughes *et al.*, 2007; Murillo, 2011). Even its initial terminology emphasised a new theorisation of learning (Hughes *et al.*, 2007), this concept has been adopted as a managerial tool in a business or corporate context (Harvey *et al.*, 2013; Soekijad *et al.*, 2004; Wolf *et al.*, 2013) and within a human resource management perspective (Engeström, 2007), emphasising the *practice* (Amin and Roberts, 2008; Gherardi, 2005).

Applicable fields are diverse, including healthcare and social services (Andrew *et al.*, 2008; Ferlie *et al.*, 2005; Gabbay *et al.*, 2003; Meagher-Stewart *et al.*, 2012; Mørk *et al.*, 2008), technology-based firms (Probst and Borzillo, 2008), the automotive industry (Wolf *et al.*, 2013), chemical, software, telecommunications and pharmaceutical organisations (Lesser and Storck, 2001), the game developing arena (Jean-François Harvey *et al.*, 2015), virtual communities (Lindstaedt, 2004) and even CoPs outside the workplace (Beck, 2007).

Recent contributions to CoP theory have focused on the concept (Amin and Roberts, 2008; Gherardi, 2005; Hughes *et al.*, 2007), how to design, launch and manage them (Amar and Coakes, 2013; Gongla and Rizzuto, 2004; Swan *et al.*, 2002), how to measure their performance (van der Meijden and Jansen, 2010), their learning boundaries (Carlile, 2003; Hislop, 2003; Swan *et al.*, 2002), and even considering CoPs as management tools (Sapsed, 2004). On the other hand, with an interdisciplinary project-based approach, König *et al.* (2013) include some insights regarding management activities taking into account the 6th Framework Programme (FP6) focusing on sustainability (König *et al.*, 2013). More recently, CoPs have been analysed with an interdisciplinary approach by characterising sets of collaborative practices (Siedlok *et al.*, 2015).

However, very little is known about the dynamics of cross-disciplinary CoPs involving different organisations and within a convergence scenario. In fact, CoP theory has been criticised for paying insufficient attention to the relations between communities (Hughes *et al.*, 2007). Previous studies do not focus on the technological transfer process of innovative high-technological products from academia through to the market.

Since it has been demonstrated that innovation development is most effective when there is a collaborative community approach (Bansemir, 2011; Shah, 2006), this study analyses a case of a cross-disciplinary CoP in the development of a medical device. The innovative process of developing a medical device for ischemia detection is analysed with regard to its challenges, having a special focus on the impact of applying CoPs in the overall process. The principal element analysed is the interaction between the practitioners within a community and therefore the process of how knowledge is managed and transferred through the learning and collaboration of CoPs involved in the development of a technological device. This study contributes to a better understanding of the managerial implications of technological transfer processes for leading innovation as well as the commercialisation of academic research, principally focused on the current need for new biomedical technologies and tools.

The paper is structured as follows. It starts with a literature review of the challenges of transferring high technology and the role that CoPs can offer in innovative ecosystems. We present the case study methodology as a research method to understand the collaborative process of the CoP involved. With this approach we seek to demonstrate the importance of cooperation and collaboration between different organisations in the healthcare domain. The following section presents an analysis of the principal challenges and initial findings of this study.

Finally, the paper suggests a cross-disciplinary model for the value cycle from academia to market followed by the discussion and conclusions.

Conceptual Background

Transferring technological knowledge in the healthcare domain

Technology and innovation is becoming highly complex and extensive (Butter *et al.*, 2014). As knowledge is considered as an embedded value in high-tech products (Dalkir, 2013), the creation and diffusion of knowledge has become an important process not only for success in the marketplace but also because of its economic scope (Amar and Coakes, 2013). This is evidenced by the economic and innovative performance scores of knowledge-based societies (Etzkowitz and Dzisah, 2007). This process extends to efficient application, creation, location, capturing, refining, and sharing knowledge, as well as to support learning and sharing best practices (Amar and Coakes, 2013). However, managing knowledge from academia to market is not an easy process (Harvey *et al.*, 2013). Most of the time, industry and academia operate in two opposite ways (Vijayalakshmi *et al.*, 2015).

Most of the existing research has focused on the human relationships that enhance technology or knowledge transfer and improve innovation performance. Some examples include the importance of university-based technology transfer organisations promoting industry-science links (Debackere and Veugelers, 2005), the multi and inter-disciplinary collaboration between university, research institutes and industry (Schummer, 2004), partnerships and training (Starkey and Madan, 2001), the collaborative relationship between medical doctors and engineers (Yoda, 2015) and the study of the agents involved in technology commercialisation: academic spin-offs, and the university–industry cooperative research centres or science parks and incubators (Grimpe and Hussinger, 2008).

Healthcare emerging innovations have to overcome some transfer challenges in order to achieve commercial success (Juanola-Feliu *et al.*, 2012). Therefore, this field should not only be assessed from a scientific perspective but also in a wider context whereby clinical benefits and economic/health outcome improvements are demonstrable (iNNOVAHEALTH Cyprus EU Presidency, 2012). According to Linton and Walsh (2008), much of the science and technology developed in research labs is not commercialised (Linton and Walsh, 2008). Particularly, nanomedicine firms have focused primarily on science and less on the commercial applications resulting in difficulty in bringing products to market (Flynn and Wei, 2005). This problem has been analysed by the European Commission, which has stated that one of the major weaknesses of Europe lies in the difficulty of transferring its knowledge base into marketable goods and services. This gap has been identified as the European "*Valley of Death*" which explains the presence of a breach between high levels of scientific performance on one hand and the minimal contributions to industrial competitiveness and new venture entrepreneurship on the other (Debackere, 2000; Flynn and Wei, 2005; Linton and Walsh, 2008; Mahroum and Al-Saleh, 2013). The overcoming of this barrier is what Flynn and Wei (2005) called "*Crossing the chasm to commercialisation*" (Flynn and Wei, 2005).

There have been some public policy implementations along with the European Framework programmes besides research and development (R&D) to resolve this issue. Since FP4, the scope of activities has also been expanded to cover training, networking, demonstration, and preparatory activities (Barber *et al.*, 2006). Currently, the latest programme, Horizon 2020 (H2020), includes a risk management strategy that comprises 9 Technology Readiness Levels (TRLs). H2020 is the biggest EU financial programme for Research and Innovation implemented by the Innovation Union and oriented to create the conditions for making Europe more competitive through research. This initiative is focused on turning scientific breakthroughs into innovative products and services. As a strategy the TRLs are a knowledge-based standard for evaluating the maturity level of a particular technology, with the aim of having a major approach to the market. TRL methodology is useful for identifying factors that could halt, delay or prevent certain medical devices from successfully transferring to clinical use. The medical device regulations dictate that only devices with a certain level of maturity can progress to commercialisation, therefore TRLs could provide a realistic assessment of the chances of translation to clinically useful devices (Tapia-Siles *et al.*, 2015).

Bridging the gap between research and market not only requires changes in the academic mindset but also rethinking involvement in the research process (Starkey and Madan, 2001). The improvement of innovation success requires access to external knowledge, which depends on the collaboration of, and feedback from, all stakeholders (Lettl *et al.*, 2006). This collaboration could be obtained through CoPs. With its creation and identification there would be less likelihood of increasing this gap, enabling a better, optimised and fast time to market technological transfer.

Communities of practice and their role in technology transfer

It is well-known that knowledge management must be built through a social and material infrastructure (Harvey *et al.*, 2013). In this document, we contextualise the social infrastructure as the people involved in CoPs and the material infrastructure as the physical and technological ecosystem, addressed in the next section. CoPs constitute this human infrastructure which is gaining recognition as an effective organisational strategy, where members create, share, learn and teach the implicit and explicit knowledge in the context of a given practice (Bertels *et al.*, 2011; Jeon *et al.*, 2011; Lesser and Storck, 2001). They are considered key elements in the transfer of technological knowledge since tacit knowledge is difficult to transmit (Bertels *et al.*, 2011; Bozeman, 2000; Polanyi, 2009).

According to Wenger and Snyder (2000), CoPs are groups of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis (Wenger and Snyder, 2000; Wenger *et al.*, 2002). CoPs can improve performance through the spread of tacit knowledge such as best practices and professional skills (Bertels *et al.*, 2011). Members of a CoP identify themselves with their community of practice and want to develop relationships with other members of their CoPs, placing emphasis on the practice of the knowledge (Amar and Coakes, 2013; Wenger, 2011).

They shape the reciprocal learning as a social process through a sense of identity, providing value to organisations (Jeon *et al.*, 2011; Lesser and Storck, 2001; Wenger and Snyder, 2000). The character and intensity of interactions and learning processes results in innovation and productivity. As a result, performance levels are being improved through the spread of best practices and professional skills (Berends *et al.*, 2007).

An important element in knowledge exchange is the ability of users to absorb the knowledge being transferred (Starkey and Madan, 2001). In this context, it depends on the ability of team members to interact productively so that relevant knowledge can be acquired, generated and circulated in a timely and cost-effective manner (Garrety *et al.*, 2004). One of the characteristics of CoPs is the rapid flow of information and propagation of innovation (Wenger, 1998, p. 125).

In a technological innovative scenario, the importance of taking CoPs into account lies in the translation of technical knowledge, but also in aligning interests and perspectives while projects move through phases of differentiation and integration (Garrety *et al.*, 2004). Originality of the resulting innovation is also influenced by the character and the extent of knowledge transfer (Dahl and Moreau, 2002), confirming the importance of this process.

Even though the CoP terminology has only been used in the business sector for the last 15 years, it has been around for centuries (Wenger and Snyder, 2000). Currently, there are a higher number of companies or organisations that are profiting from this strategy (Murillo, 2011). However, they are not called CoPs in all organisations (Wenger, 2011, 2004). There is still a lack of specificity and unresolved issues associated with the concept and also, a considerable confusion between CoPs and other social structures (Hughes *et al.*, 2007; Murillo, 2011). Indeed, CoPs are also known under the names: learning networks, thematic groups, or tech clubs. (Bate and Robert, 2002). However, not all structural interaction networks in organisations can be labelled as CoPs (Wenger, 1998); they could be formal work groups, project teams or informal networks (Bate and Robert, 2002).

Innovative ecosystem with a community-based perspective

Beyond the capacity to create and share knowledge, CoPs also play a central role in technological innovation (Berends *et al.*, 2007; Brown and Duguid, 1991). Technological innovation could be accomplished through collaborations among researchers embedded in a growing knowledge community (Hu, 2013) but it also requires interaction and connectivity between multiple actors (entities or stakeholders) involved in the innovative ecosystem (Juanola-Feliu *et al.*, 2012; Páez-Avilés *et al.*, 2015; van Looy *et al.*, 2004). In the healthcare domain, this process is particularly important due to the fact that this is a global process with social implications (Milbergs and Vonortas, 2005). An example is the *personalised medicine* which is projected to have a major impact in the future of healthcare (Gaspar *et al.*, 2012). In this regard, the rise of Point-of-care (PoC) testing is expected to drive innovation in health systems by improving patient flow within clinics, increasing testing rates, and resolving health system bottlenecks so that the tests can be successfully used (Jani *et al.*, 2013).

Collaboration is one of the key factors in the success in creating and developing medical devices (Yoda, 2015), and activating the business sector (Hagedoorn, 2002). CoPs play an important role not only in knowledge management, and the whole knowledge management lifecycle, but also in the innovation process (Du Plessis, 2008). The integration of knowledge is the key element for the implementation of technological innovations. In this context, Hislop (2003) argued that CoPs have a bi-directional relationship with the implementation of inventions and innovations (Hislop, 2003). One of the most significant ways in which the CoPs affect the innovation processes is through the way they influence attitudes and behaviours of their members/participants (Ferlie *et al.*, 2005). Therefore, implementation of technological innovations involves the mutual adaptation of the technological system being implemented, and the organisational context within which they are being introduced (Brown and Duguid, 1991).

Transfer of knowledge from research and science communities to commercial stakeholders is a function of research centres, academia, institutions, governmental bodies and industries (Kalisz and Aluchna, 2012), which also need cooperation and commercialisation agreements in order to facilitate shortest times to market (Dogramatzis, 2010). CoPs promote knowledge generation and learning across organisational and spatial settings (Amin and Roberts, 2008) and within organisations. CoPs support some important activities: they drive the company‘s strategy, start new lines of business, solve problems quickly, transfer best practices, develop professional skills, and help companies to recruit and retain talent (Swan *et al.*, 2002; Wenger and Snyder, 2000). These advantages are the result of voluntary, natural (Wenger and Snyder, 2000) and informal interaction between people sharing the same motivation. This means that, unlike project teams, or formal work groups, they organise themselves (Wenger and Snyder, 2000). This "self-selectivity" suggests that CoPs can emerge in diverse contexts, namely, virtual/online (discussion groups and blogs) (Füller *et al.*, 2006) and in real life (any field setting) (Borzillo and Kaminska, 2013; Wenger and Snyder, 2000).

In this context, CoPs have three characteristics: they need a *domain* which is the area of their knowledge; a *community*, which is the group of people for whom the domain is relevant; and the *practice*, which includes the body of knowledge, methods, tools, language, stories, cases, and documents which members share and develop together (Wenger, 2001). According to Wenger (1998) the practice is the source of cohesion of the community and this evolves as the result of the learning process and the common routines (Wenger, 1999). On the other hand, the source of coherence is typified by three dimensions: *Mutual engagement, a sense of joint purpose and a shared repertoire* (Wenger, 1998, p. 73). According to Lathlean and Le May (2002), this dynamic process depends on some factors that influence

Table 1. Factors that influence the development, functioning and maintenance of a CoP.

Factors	Characteristics
Membership	Members initially are self-selected. People participate because they personally identify with the community.
Commitment	Related to the desired goals and from outside the community. It is important that members could see the importance of progress towards the goals.
Relevance	Members need to see the purpose and potential of the work of the communities, especially with respect to the extent to which it was helping to address real issues that were a priority for service development.
Enthusiasm	Members feel that progress is made in and between the CoP meetings. Enthusiasm is likely to be linked to the actual potential to make changes.
Infrastructure	Supports the work of the CoP in terms of ease of access to knowledge or evidence
Skills	Improving skills while accessing and appraising a variety of sources of knowledge.
Resources	Allows achieving the desired change that goes beyond time needed to meet, seek information or canvas support.

the development, functioning and maintenance of an inter-organisational CoP (Table 1) (Lathlean and Le May, 2002).

Moreover, in medicine there is a demand to ensure close cooperation between University–Hospital–Industry–Administration so that specific tools and procedures can be developed by clinicians (Juanola-Feliu *et al.*, 2012; Leydesdorff, 2011). In this ecosystem, universities (academia) are the source of knowledge, which can be used as a competitive advantage for firms (Grimpe and Hussinger, 2008; Liebeskind, 1996). Therefore, universities are key elements in the innovation ecosystem, and an important aspect of their involvement is the role they play in public–private partnerships (Hall *et al.*, 2003).

Research Aim and Methodology

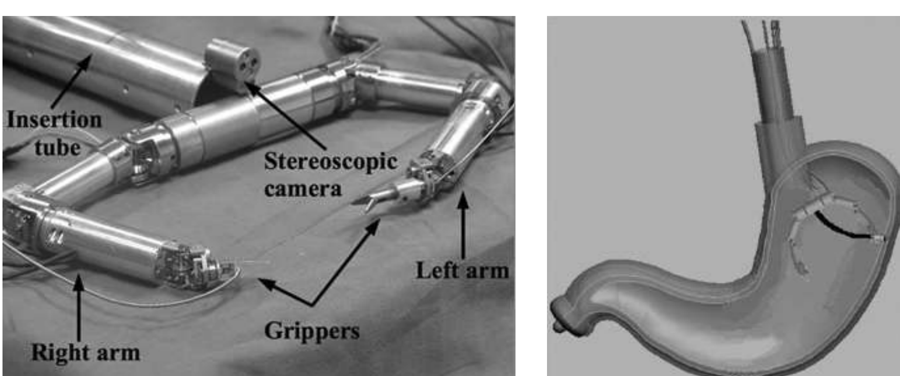
A better understanding is needed regarding how the gap in the process of transferring medical devices from academia to the market could be successfully overcome when high-technology is intended to be commercialised. In an attempt to explore this issue the following question emerged: *how can a cross-disciplinary CoP foster innovation and technology transfer of high-tech products*? Using an illustrative case study, this document examines a new sensor array technology for ischemia detection developed by the University of Barcelona. We analyse the strategic activities developed in order to bring an innovative medical device onto the market. The case study approach was considered to be the most appropriate for this research since this method is used for analysing group behaviours (Halinen and Törnroos, 2005; Saunders *et al.*, 2009) with the aim of building a rich deep understanding of new phenomena (Christie, 2000; Johansson, 2003; Robson, 2002; Yin, 2014). The rationale for selecting this single case study rather than multiple cases is that this single case can represent a significant theory (Yin, 2014). The inductive element this study tries to uncover is to understand how a CoP is involved in the innovation and the technology transfer process for the development of a medical device. This case is aligned with the current trend of developing cross-cutting Key Enabling Technologies (KETs) for obtaining innovative products, especially in the healthcare domain (Páez-Avilés *et al.*, 2015).

Case description: ischemia monitoring array medical device

The case studies an innovative ischemia-detecting device that shapes and sizes a sensor array prototype. It was designed for the detection of ischemia inside the stomach by means of endoscopic tools. The device was developed through the collaboration of CoPs involved in an innovation ecosystem.

Ischemia is a hypoperfusion of the blood through an organ or tissue caused by a pathologic constriction or obstruction of its blood vessels, or an absence of blood circulation. It can occur in any part of the body, but is especially relevant in the brain, heart, bowel and stomach. Findings suggest that 80% of all strokes produced in the brain are due to ischemia, causing 9% of deaths from strokes around the world. The cost of stroke worldwide is around 2–4% of total health care costs. Currently, ischemic heart disease (IHD) is the leading cause of death worldwide. By 2020, IHD is projected to be the most common disease causing death (Menken *et al.*, 2000). Additionally, various surgical procedures for morbid obesity such as gastric banding, sleeve gastrectomy, gastric bypass and visceral operations such as bariatric and esophageal surgery can result in tissue ischemia and arterial demarcation even though these procedures are considered safe and have reproducible therapeutic results (Stamou *et al.*, 2011; Tahirbegi *et al.*, 2014).

Real time detection methods on the organ tissue are needed for early detection of ischemia, since a prolonged ischemic condition causes severe tissue damage and failure of organs (Tahirbegi *et al.*, 2013). However, there are few commercial products available. Unfortunately, remarkable developments in medical and surgical aspects cannot help to improve the diagnostics of this disease (Oldenburg *et al.*, 2004). Ischemia detection is difficult in organs such as the stomach, since the low pH in the gastric juice makes it challenging to fabricate stable and functional all-solid-state pH sensors (Quentin *et al.*, 2006; Tahirbegi *et al.*, 2013). The electrochemical sensor device uses an electrode insulated with a commercial biocompatible resin, being resistant to the stomach pH. Additionally, the device created is 4 times less expensive that commercial equipment, easy to mass produce, of small size (portable) and applicable to endoscopic systems. Figure 1



(a) (b)

Fig. 1. Medical device for ischemia detection. (a) Parts of the device and (b) representation of the functionality.

shows full integration of the ARAKNES devices for performing scar less robotic surgery with continuous control of the patient's ischemia.

The cross-disciplinary CoP in the ecosystem

The development of high-tech products requires the improvement of technology and the decrease of micro/nanofabrication costs from basic, as well as from applied research. In order to achieve these goals researchers, companies and entrepreneurs have the opportunity of working within a cooperative ecosystem. The complete overview of the value chain of research and technology transfer processes highlights the importance of a common framework in which multidisciplinary teams and organisations can work together directed by determined scientific leadership focussed on CoPs.

In this particular case, a new and innovative ischemia sensor is the result of a multiple and complementary participation and collaboration of key stakeholders involved in biomedical research and innovation: the Department of Electronics at

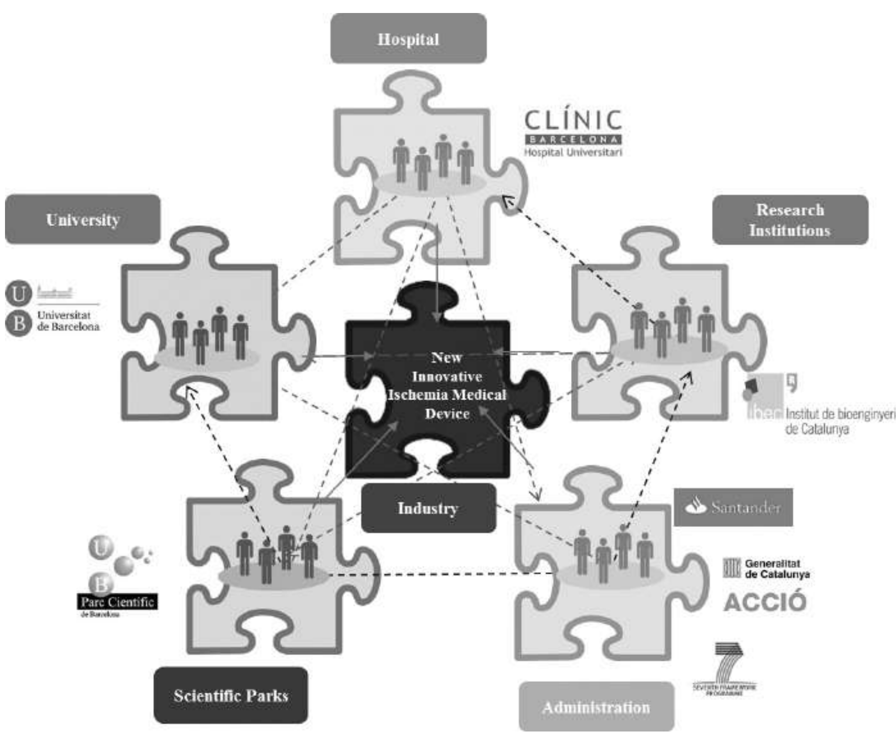


Fig. 2. Communities of Practice involving the different stakeholders for innovation and technology transfer in the development of an ischemia detection medical device.

the University of Barcelona, the Institute for Bioengineering of Catalonia (IBEC), the Clinic Hospital, the UB Scientific Park and the Biomedical Research Networking Centre in Bioengineering, Biomaterials and Nanomedicine (CIBER–BBN). Figure 2 shows this particular scenario where interactions between different CoPs are represented by the broken line.

In this scheme, the medical device was obtained through the collaboration of the university, scientific parks, research institutions, hospitals and administration (public policies). Consequently, the device is able to offer the industry the opportunity to scale and pre-commercialise. This scheme could be extrapolated to the development of any medical high-technology product.

Initial Findings

Overcoming technology transfer challenges

Beyond identifying the principal CoPs, three transfer challenges from this particular technology were also considered. Wegner stated that CoPs are the combination of three elements: community, domain, and practice. These three elements have been analysed for this case study and are illustrated in Table 2. First, the shared area of knowledge, denominated the domain, is characterised to be interdisciplinary, meaning that the community had one common focus, but viewed from different perspectives. This facilitated creative ideas and the optimisation of problem solving. Second, the community was intra-organised. This allowed the involvement of multiple organisations or institutions together allowing economic support between them. Finally, the practice is characterised to be profitable, meaning that commitment relationships, good interactions between practitioners and initial contact with end user drive a better availability analysis of the device and a better knowledge transfer. In practical terms, bureaucracy can be reduced.

A multidisciplinary work environment resulted in the understanding of different points of view from people with different backgrounds (medicine, electronics, mechatronics, chemistry, physics, and biology), thus achieving a completely different approach to facing problems. It also helped by breaking fixed routines and preventing narrow thinking in a pre-determined way according to academic or social background. Although there are deep interdisciplinary collaborations from different groups, especially in Europe with FP7 and H2020 projects, researchers need to understand the necessities of the industry and the achievements in basic research. Besides, interdisciplinary-formed personnel are also essential, so they can understand the diverse sciences, understand needs and speak the same technical language. In other words, they can be a "translator" between different

Table 2. Essential characteristics of CoPs for developing innovative medical devices.

CoP element	Description	Key characteristics	Outcomes
Domain	A shared domain of interest. The area of knowledge that brings the community together, gives it its identity, and defines the key issues that members need to address.	Interdisciplinary: It must have one common focus, but viewed from different perspectives.	Optimisation of problem-solving and creativity
Community	Group of people for whom the domain is relevant, the quality of the relationships among members, and the definition of the boundary between the inside and the outside.	Intra-organised: It must involve organisations or institutions together allowing economical support between them.	Cost-reduction of intellectual property
Practice	The body of knowledge, methods, tools, stories, cases, documents, which members share and develop together.	Profitability: Commitment relationships, good interactions between practitioners and initial contact with end user drives a better availability analysis of the device and a better knowledge transfer.	Bureaucracy reduction

languages such as physics, chemistry, biology, electronics, software etc. This is the first recommended characteristic of a high-tech CoP.

Second, the FP7 ARAKNES project developed the implantable ischemia sensor in close contact with physicians. For *in vivo* applications, numerous permissions are needed, as well as animal or human experiments. This process takes years and the costs of these experiments are extremely high. Thus, it is nearly impossible for a university or small company to invest in it. In this context, this experience suggests an intra-organised process which allows economic support between the stakeholders.

Finally, in the case of a successful high tech product, protecting the invention through a patent application is required. However, the cost of patentability is quite high. In this context, a profitability analysis may give information about the cost-effectiveness of the project, from its first to last stages. The patenting issue is also another limiting factor. If you have an innovative idea, the idea will be built on (as it should be) the work of others. However, if you would like to develop a device, you need to use previously developed systems as a starting point. In general, all these platforms are patented, making the process even longer. Current examples with an increasing interest in industry are blood tests for PoC applications (Punter-Villagrasa *et al.*, 2015). They require plasma separated from blood; however, cheap plasma separation systems are patented. Continuous contact and feedback during the development of the device from the end user will determine the path of the research. Thus, it will increase the success rate and optimise the time of the overall process in terms of bureaucracy.

Wegner's three elements of CoPs give a global characterisation of the community. However, individually each one of the different communities represented as a puzzle piece in Fig. 2 has other challenges when interacting with the other communities. The principal challenges are due to the diverse background and expertise of members. Depending on the organisation they come from, different activities should be agreed and coordinated. Each community, their activities and their technology transfer challenges are depicted in Table 3.

New attention is now being focused on the boundaries between professional groups, individual professionalism and associated CoPs (Ferlie *et al.*, 2005). Amin and Roberts (2008) have characterised different varieties of situated knowing with over-lapping dynamics: Craft/task knowing, virtual knowing, professional and epistemic knowledge. Our case can be contextualised as a professional community without dismissing the craft and epistemic knowledge (Amin and Roberts, 2008). The professional knowing related to the mastery of tacit and codified knowledge is more focused on the healthcare sector. In addition, the nature of innovation for this characterisation is that innovation tends to be incremental rather than radical.

Table 3. Characteristics, activities and technology challenges of the different CoPs from this case study.

CoP	Characteristics	Community activities	Technology transfer challenges
University	Principal members are academics, PhD and Master's students from the Faculty of Physics with the speciality of bioengineer. They are more involved in the first stages of product development.	Basic research, especially for impedance experiments.	Academics need to be aware and informed about the needs and challenges for physicians and the characteristics of the disease.
Scientific Park	Technicians with expertise and knowledge in the machines owned by the scientific park.	Fabrication process and experimentation.	A clear technical language poses a fundamental challenge for other communities.
Hospital	Formed by surgeon physicians with experience in ischemia.	Guidance in the experimental *in vivo* stage of the research.	Medical terminology and language need to be transmitted and understood by the other communities.
Research Institution	Members include researchers and technicians with skills in protocols and technical procedures. They are also in charge of different projects.	Robotic and pressure sensor experimentation.	Efficient transfer of basic research to technology development addressing the needs of all CoPs.
Administration	Project managers with expertise in finance, management and policies.	Auditing, monitoring and stretching the focus of the research.	The principal objective and focus of the research must be maintained and encouraged. Flexibility in bureaucracy is also a time-challenge for this CoP.

A cross-disciplinary and integrated model

In this particular case study, the device was the result of an interdisciplinary co-working. The resulting CoP was composed of technicians, innovation managers, researchers, engineers, physicians, and project managers. The way in which this structure was organised, expands beyond the traditional, structural (Lesser and Storck, 2001; Wenger, 1998), spatial (Wenger, 1998), networking (Jewson, 2007), or knowledge boundaries (Ferlie *et al.*, 2005). In this context, Wenger (1998) argues that the limitations of the organisation are not necessarily the limitations of the CoP, therefore they "*cannot be considered in isolation from the rest of the world or understood independently of other perspectives*" (Wenger, 1999: 103). Sharing knowledge outside the traditional structural boundaries allows the participation of one member in multiple CoPs at once (Wenger, 1998: 105), and this particular organisation is considered to be an effective way to handle unstructured problems (Lesser and Storck, 2001).

It has been shown that uni-professional CoPs, especially in the healthcare domain, face obstacles in spreading innovations. They develop internal learning and change but also produce strong social and cognitive boundaries blocking external learning sources. Therefore, the identification and management of social and cognitive boundaries between different CoPs are important (Ferlie *et al.*, 2005). According to Adler and Heckscher (2006) a communitarian-based organisation generates and shares knowledge as a primary benefit. In fact, in modern industry, a wide range of competences and knowledge bases are needed, meaning that this cannot be reached through the usual "teamwork" (Adler and Heckscher, 2006). What determines the texture of ties or trust is not spatial proximity, but the nature of contact, intermediation, and communicative complexity involving groups of actors and entities (Amin and Roberts, 2008).

As CoPs are not defined or determined by a particular spatial form (Lave and Wenger, 1991), one individual can simultaneously belong to several communities (Alison, 2007; Wenger, 1999). The resulting flow of knowledge from other communities from different backgrounds influence the level of innovation and the cross-fertilisation of ideas (Kodama, 2007). Moreover, Amin and Roberts (2008) stated that when related professions intersect in a professional CoP, innovation and creativity seems to be stronger, therefore novelty comes from fusing elements not connected before. They manage and generate conflicts as a result of the cross-cutting alliances (Hughes *et al.*, 2007).

Practices of the different CoPs are interdependent. According to Mørk (2008) the learning process required for the development of high quality procedures requires that each CoP can learn in coordinated ways. This implies that, they need to learn *cooperatively* aligning the practices of one CoP with the practices of other

CoPs (Mørk *et al.*, 2008). The present study argues that, beyond the importance of cross-disciplinarity for developing a medical device, members from the different communities can be joined together in a new CoP from the very beginning of the development value cycle. In this context, Wenger refers to this integrative activity as "*constellations of practice*", referring to multiple interlinked communties which can be overlapping or nested in some way (Wenger, 1999).

The complete overview provided here of the value chain of research and technology transfer processes highlights the importance of a common framework in which multidisciplinary teams and organisations can work together directed by determined scientific leadership (Juanola-Feliu *et al.*, 2012). This case study proposes that the value is generated when the different communities are integrated from the first step of the value chain, meaning that they are not transfering the technology separately, but together from research to market. The result of this process is the generation of new ideas/knowledge for product development and time optimisation of the overall process (Fig. 3).

The proposed integrated model argued that facilitating technology transfer from the academic to commercial sector requires the active involvement of the different communities from the beginning of the process and continuing the social interaction up to the point of commercialisation of the medical device. Timelines vary dramatically across the nature of the medical device according to the level of complexity. Generally these types of devices take five or more years to obtain a

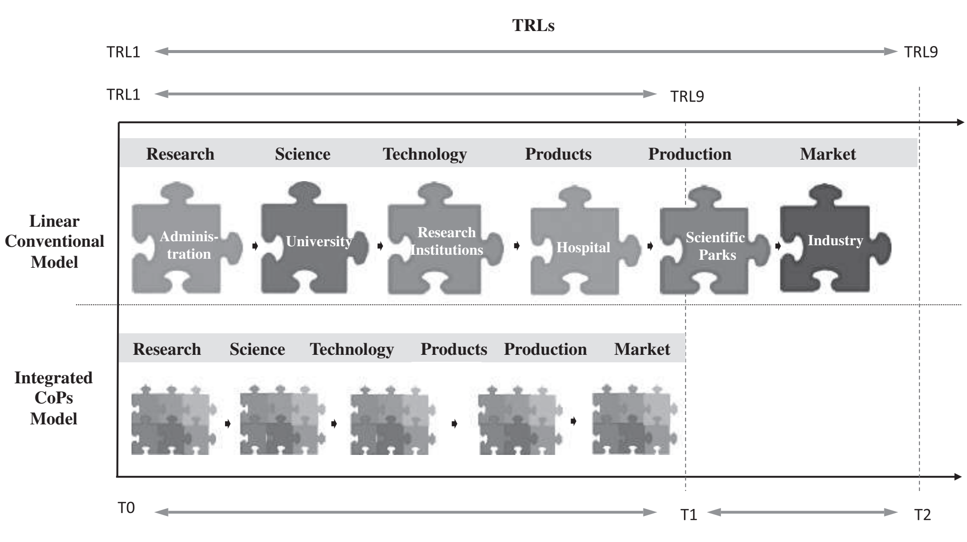


Fig. 3. Time comparison scheme of the conventional model and the integrated model of the cross-disciplinary CoP approach in the value cycle.

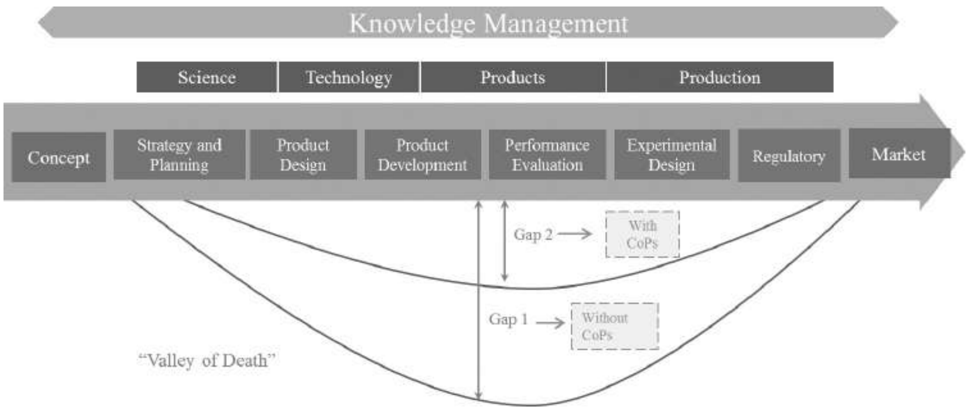


Fig. 4. The value cycle of medical devices. A comparison of scenarios with and without CoP.

product before the regulatory process (Zenios *et al.*, 2009). Here this complex medical device has been achieved in four years.

However, time is not the only variable that is successfully reduced in this case study. TRLs were also achieved in less time (Fig. 3). When using the innovation model of a CoP, the product readiness could be achieved in less time than in a conventional model. The overall proposed model suggests that this gap could be reduced with the participation of integrated CoPs (Fig. 4).

Discussion

Social demand and the existing changing marketplace require sustainable, competitive and accessible products or processes based on creativity and innovation. It is known that knowledge and technology are key drivers of competitive advantage, not only at company levels but also in national and regional contexts. Furthermore, knowledge produced in the public sector has been found to be an important ingredient of economic growth and technological progress (Adams, 1990). This knowledge is produced at a high rate by universities, which own different disciplines and specialties (Hsu *et al.*, 2015). It has been shown that CoPs play an important role not only in knowledge management, and the whole knowledge management lifecycle, but also in the innovation process from universities (Du Plessis, 2008). A well-established managerial strategy for this knowledge could forge links between academic research and commercialisation.

Once embedded into a biomedical device, the knowledge and technology introduced in this paper could improve the speed of diagnostic information for better diagnosis, treatment and patient quality of life. Therefore, new emerging technological innovations should not be assessed only from a scientific perspective.

Doubtless there is an increasing interest within the research organisations in fostering the process of knowledge and technology transfer while value-adding activities are embedded at the R&D stages. As a result, new research and market challenges could be reached through technological innovation, contributing to the improvement of industrial competitiveness and regional economic growth and at the same time to public health and quality of life of the patients.

Overcoming the gap between research and market could be a difficult process if some transfer and market challenges are not considered. Important factors that could help in crossing the valley of death include deconstructing the process of how knowledge is managed and transferred through CoP's learning and collaborative actions. Additionally, it is important to analyse and evaluate the high-tech activities and the stakeholders from a commercial demand perspective for a better knowledge and technology transfer of the product.

The complete overview of the value chain of research and technology transfer processes highlights the importance of a common framework in which multidisciplinary teams and organisations can work together directed by determined scientific leadership in the context of a CoP. In this particular case, the device is the result of multiple and complementary participation: the Department of Electronics at the University of Barcelona (academia) has had overall charge of the R&D activities, followed by the experimental proof of concept and the subsequent prototyping by CIBER–BBN (public institution) with the economic support of the Botín Foundation — Santander Bank (private funding) which joins the value chain when clinical research and commercialisation are considered.

Managerial implications, limitations and future perspectives

Key factors explored through this case study analysis are essential to the success or failure of particular diagnostic tests in getting to market and to the intended end users. In this context, the gap has been reduced and the product prototype has reached a closer approximation to its commercialisation by replacing the traditional linear model for an integrated CoP model as a knowledge management strategy within academia.

This multidisciplinary case study provides a deeper understanding of the role of CoPs within a technology convergence scenario. It makes a contribution at two levels: a more scientific level and a managerial level. The factors we have highlighted emphasise implications for open innovation research as well as for allowing innovation managers, technology transfer responsibility and public-funded research institutions to gain knowledge and become more conscious in identifying the corresponding communities for innovation management and technology transfer. Thus, the concept of CoPs could become a useful tool for promoting innovation since it is the best manner of interacting with a common language guided by the same interests, optimising in this way the technological transfer process.

Furthermore, this contribution could be extended to emphasising the information and communications technology (ICT) challenges that such sensor-devices pose when it comes to capturing data, aggregating information about patients, and sharing knowledge among surgeons, nurses and family. In addition it could be useful in discovering the true nature of enterprise knowledge and workspaces, capturing the local work context which can only be expressed in graphical language, or taking advantage of graphic modelling for collaborative networking to break down the horizontal and vertical sliced activities that hinder data and situation driven collaboration and innovation.

This research is not exempt from limitations. In particular, the single case study restricts generalisability. Therefore, future directions could focus on testing the suggested model taking the time and the TRLs as variables in other fields or industries. In addition, taking into account user innovation-communities in medical devices would be an interesting field of research in this line. Cultural obstacles and other related challenges for a cross-disciplinary CoP can also be important approaches to be identified, as well as the creation of the best conditions for the generation of CoPs.

Conclusions

This study describes the mechanisms that enable tacit knowledge transfer through a CoP in fostering technological innovation in a multi-stakeholder ecosystem. Although the case study reported in this paper is complex because it involves multiple organisations, it contributes to extending experience of high-technology applications and their commercialisation. Moreover, this case study could provide a basis for applying solutions to commercialising array-based sensor products by understanding the complex real-life situations and learning from the everyday experience of facing market challenges. Additionally, the present study aims to contribute to the scarce literature when a framework of convergence of technologies is taken into account; sharing best practices in this process for a better understanding of the impact of integrating and reshaping the concept of CoP in technology transfer and innovation activities.

Thus, the concept of CoPs is a useful tool for promoting innovation, reducing the gap between, and optimising the time from research to market. This suggested model contributes to the interaction guided by similar interests, fostering innovation and technological transfer process of medical devices.

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