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Contents

The construction industry and the circular economy

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Abstract

The concept of the circular economy is increasingly seen as a major policy agenda item and a testing challenge for the construction industry within Europe. This short case study outlines the characteristics of the circular economy, provides an exploratory review of how some companies and industry bodies within the construction industry in Europe are publicly addressing the concept of the circular economy and offers some general reflections on the application of the concept within the construction industry. The findings suggest that while some of the major construction companies within Europe are currently looking to integrate circular economy thinking into their strategic planning and a number of them have reported on innovative and experimental initiatives, the widespread and comprehensive translation of such thinking into construction practice is still at an early stage. At the same time the authors suggest that the widespread adoption of the concept of the circular economy within the construction industry will face a number of challenges. More contentiously, there must be concerns that the major construction companies might effectively capture the concept of the circular economy to justify continuing economic growth.

Keywords: Circular economy; circular business models; European construction industry; product life cycle.

Introduction

The concept of the circular economy is increasingly seen as a major policy agenda item and a testing challenge, for the construction industry within Europe. The European Commission (2018, webpage), for example, argued that 'the built environment is a key target' in its 'policy for circular economy' and the European Environment Agency (2016a, webpage) identified construction and demolition as one of five priority areas in the transition to a circular economy. The European Construction Industry Federation (2016, p.1) reported that it 'strongly supports action that will make the circular economy a reality' but argued that 'for the circular economy to become a reality, there needs to be greater acceptance in the relevant markets and both the supply and demand side need to be addressed.' The UK Green Building Council (2018, p.1) argued 'circular economy is a term and a concept that has risen rapidly up the agenda for property and construction professionals, but all too often it challenges the status quo and has struggled, as a concept, to progress.' The UK Green Building Council (2018, p.1) further suggested that 'despite several organisations leading initiatives to raise awareness and encourage circular thinking, many construction and property professionals are still struggling to apply true circular thinking to their business models, services and products.'

While some of the major construction companies within Europe are currently looking to integrate circular economy thinking into their strategic planning and a number of them

have reported on innovative and experimental initiatives, the widespread and comprehensive translation of such thinking into construction practice is still at an early stage. This might be seen to be reflected, for example in company, Bam (2018, webpage), the Netherlands based construction company, reporting on continuing 'to get to grips with the circular economy' as part of its vision for building a more sustainable future, in Vinci (2016, p. 180), the French headquartered international construction company, reporting setting up 'a centralised focus group to advance its study of the circular economy' and in Interserve (2016, p. 38), the UK based construction company, reporting on continuing 'to support the development of circular economy thinking.' With these comments in mind this short case study outlines the characteristics of the circular economy, provides an exploratory review of how some companies and industry bodies within the construction industry in Europe are publicly addressing the concept of the circular economy and offers some general reflections on the application of the concept within the construction industry.

The Concept of the Circular Economy

Murray et al. (2015, p. 10) suggested that the term circular economy has 'been linked with a range of meanings and associations by different authors' and Kirchherr et al. (2017) identified 114 definitions and argued this 'variety of understandings can result in CE concept eventually collapsing or ending up in conceptual deadlock.' The Ellen McArthur Foundation, established in 2010 with the aim of accelerating the transition to a circular economy, argued that 'a circular economy is restorative and regenerative by design, and aims to keep products, components, and materials at their highest utility and value at all times' and that 'the circular economy is a continuous, positive development cycle. It preserves and enhances natural capital, optimises resource yields, and minimises system risks by managing finite stocks and renewable flows' (Ellen McArthur Foundation 2017, webpage). The Ellen McArthur Foundation and Granta Materiality intelligence (2015, p.1) define 'a circular economy' as 'a global economic model that aims to decouple economic growth and development from the consumption of finite resources.' Equally ambitiously, the US Chamber of Commerce Foundation (2018, webpage) defined the circular economy as 'a restorative model that decouples economic growth from natural resource use, and emphasizes longevity, reuse, and recycling. All resources and energy are renewable and regenerative, all durable resources are endlessly cycled back into supply chains, and waste does not exist.'

Typically, the concept of the circular economy is contrasted with the traditional 'linear economy' which turns raw materials into waste in the production process and which is seen to lead to environmental pollution and the removal of natural capital from the environment. In theory the concept of the circular economy embraces all stages of the product life cycle from both the product design and the production process, through marketing and consumption to waste management, recycling and re-use. Within such an economy an initial focus on designing products that are more resource efficient throughout their life cycles can make products more durable, easier to repair and to recover constituent, and potentially still useful, materials from the products when their initial lifespan is over. As long as the majority of environmental costs are borne not by producers but more generally by a potentially wide range of stakeholders then there is limited incentive to introduce more innovative design thinking. The circular economy also demands greater efficiency in production processes and here the focus is on looking to reduce the environmental and social impact of production, for example,

through more sustainable sourcing and the promotion of innovative industrial processes.

A variety of potential economic and environmental benefits are claimed for a transition to a circular economy. The World Economic Forum (2014, p.13), for example, estimated that globally the circular economy is a 'trillion-dollar opportunity with huge potential for innovation, job creation and economic growth.' While the European Commission (2018, webpage) argued that the 'circular economy offers an opportunity to boost our economy, making it more sustainable and competitive in the long run.' McKinsey and Company (2015, webpage) argued that a circular economy 'would allow Europe to grow resource productivity by up to 3% annually' and that it could generate a net economic benefit of 1.8 trillion Euros by 2030. More specifically EY (2015, p.10) suggested that 'the circular economy helps to contain risks', for example, in managing raw material supply in competitive markets, and in providing opportunities to 'extend and strengthen customer relationships', 'tap into new markets', 'become more efficient' and 'yield extra income.' On the environmental side, Het Groene Brein (2016, webpage) argued that 'the initial target for the circular economy is to have a positive effect on the ecosystem and to counteract the overload and the exploitation of the environment. The circular economy has the potential to result in a reduction in emissions and use of primary raw materials, an optimization of agricultural productivity, and a decrease in negative externalities.'

A number of factors help to explain the pressure for the transition to a more circular economy. These factors include the continuing depletion of scarce natural resources, the supply problems associated with the increasingly volatile international political situation and the unpredictable events associated with climate change, and the potential price volatility associated with both these factors. At the same time, the continuing environmental degradation and natural resource depletion associated with the current dominant traditional business model, the increasing introduction of national and international statutory legislative regulation designed to reduce environmental problems, and investment in technological innovations, which promote the more efficient use of natural resources, are all important drivers for a circular economy. More generally, indications of the emergence of new strategic corporate thinking that recognises the imperatives of business continuity will encourage the adoption of new and more resilient business models.

However, while 'some companies are beginning to test circular economy principles in their business models' (UPS and Green Biz 2016), there are major challenges in measuring how effectively and economically a company is making the transition to a more circular business model. Such challenges in part reflect the variety of meanings attributed to the concept and to 'the complexity and variety of actions, activities and projects that could be called circular' (US Chamber of Commerce Foundation 2018, webpage). Currently, there is no universally agreed framework to enable companies to measure their progress in working towards a circular business model but a number of approaches can be identified. The US Chamber of Commerce Foundation (2018, webpage), for example, suggested that 'a complete accounting of all activities, at least early on, is not necessary to communicate about how a circular program is progressing.' Rather the US Chamber of Commerce Foundation (2018, webpage) advised that 'the initial focus of program measurement should be on measuring attributes or activities that reflect circulating materials through the supply chain rather than using virgin materials or disposing of products in a landfill at the end of their useful

life.' The Ellen McArthur Foundation and Granta Materiality Intelligence (2015 p. 4) have developed a methodology to provide 'indicators to estimate the circularity of products and businesses' and initially these indicators 'focus exclusively on technical cycles and materials from non-renewable sources, as their circularity strategies and associated business benefits are better understood.'

Approaches to the Circular Economy within the European Construction Industry

The construction industry in Europe is approaching the concept of the circular economy in a variety of ways and thinking amongst companies, industry bodies and consultants is evolving over time. Ideally the circular economy should involve the whole of the construction supply chain but in many ways the main thrust of the initial approaches have been dominated by a focus on waste and recycling. Ferrovial, the Spanish based construction company, for example, created a circular economy working group in 2016 'to identify and promote opportunities for transforming waste produced and managed' by its two divisions 'into raw materials or secondary fuels, which can subsequently be used in other works and infrastructures designed, built and operated by Ferrovial' (Ferrovial 2016, webpage). Under the banner 'Make Waste a Thing Of the Past', Interserve (2016, p. 36) reported that its next priority was 'engaging with a wide range of stakeholders…. to discuss closed loop systems and the circular economy.' Vinci (2018, webpage) reported that the company's general policy on waste and recycling 'is geared to the circular economy.' In addressing 'resource efficiency and waste minimisation' Skanska (2017, webpage), the Swedish based multinational construction company, recognised that 'significant opportunities exist in construction to prevent waste from occurring' and reported that 'we operate in line with the waste hierarchy and are working on several initiatives which aim to eliminate waste to landfill and promote the circular economy.'

More generally Arup and Bam (2017, p. 9) suggested that construction and demolition waste accounted for 25-30% of all waste arising in the European Union. More ambitiously Arup and Bam (2017, p. 9) claimed that 'by adopting circular economy business models' the company will not only 'help businesses save on raw material costs and waste management costs' but also that there 'will be little or no waste to landfill and environments will be enriched by biological nutrients reintroduced into the biosphere through composting and bio-digesters.' The Construction Products Association (2016) has identified a number of mechanisms by which construction products and materials can be reused. Salvo, for example, trades in France, Germany, Netherlands, Ireland and the UK, and offers a reclamation service for architectural antiques, doors, fireplaces, ironwork, lighting, radiators, windows and stained glass. There are also a growing number of material exchanges and a variety of community reuse schemes.

However, van Sante (2017, p.5) stressed that 'circular construction is more than recycling' and argued that 'circular construction involves the entire construction supply chain.' Further, van Sante further argued circular construction 'is not only working out how the materials can be best reused when a building is demolished' rather 'in circular construction, architects, engineers, and contractors take minimising the use and maximizing the reuse of entire buildings and/or building materials into account at the very start of the construction process.' If circular construction is to become a reality then the entire construction supply chain will have to be involved. In proposing that

'there are many different ways to make construction circular', van Sante (2017) argued that 'circular construction starts with circular design.'

Arup and Bam (2017, p. 24) suggested that building circular design into projects at the initial 'development and planning phase of a built asset' offers an 'opportunity.' Such opportunities are seen, for example, in that 'products, systems and the entire build structures are designed to last longer with a higher residual value' and that 'they shall be easier to maintain, repair, upgrade, refurbish, remanufacture or recycle with respect to traditional ones' (Arup and Bam 2017, p. 24). At the same time (Arup and Bam 2017, p. 24) suggested that 'new materials can be developed and sourced, particularly bio-based, that are less resource intensive or fully recyclable' and that 'there is an opportunity for designers to engage with potential partners who may have an interest in the development of post initial use.' Toyne (2016) has provided some illustrations of how Balfour Beatty employed a circular design approach in using King Sheet Piling on the M25 widening project and the A421 improvement project in the UK and claimed significant savings in the steel used and reductions in carbon dioxide emissions.

In the Netherlands Bam employed circular design principles in the construction of a new town hall extension for the municipality of Brummen. Here the local authority commissioned a building for a service life of just 20 years and Bam designed a building for disassembly. The extension's modular design will not only enable easy disassembly and some 90% of the materials in the newly added space can be dismantled and reused at the end of the extension's service life. In the UK the Queen Elizabeth Olympic Park in London, originally used for the Olympic Games in 2012, was also designed for reuse though here long delays between the original planning and design stage and the eventual transformation meant that not all the proposed new features materialised. More generally within the UK, the Construction Products Association (2016, webpage) claimed that 'whilst many buildings/infrastructure projects are designed with sustainability principles and may incorporate aspects of the circular economy, there are few examples as yet of the "full" application of circular economy thinking.' At the same time the Construction Products Association (2016, webpage) also claimed that 'a reasonably high level of understanding of the generic principles of designing for deconstruction exists but there seems little commercial appetite for doing it.' More positively the Construction Products Association also reported that the Building Research Establishment has generated number of case studies to help increase awareness amongst designers, architects and contractors of how the construction industry can unlock the benefits of the circular economy and that the Association of Sustainable Building Products have a website that provides information on designing for deconstruction.

While design can be seen as the first step in the circular construction process van Sante (2017, p. 7) suggested there were 'many different methods to make construction circular.' These methods include maximising the life span of a building; designing buildings with fewer materials; using bio-based construction materials; using buildings that have come to the end of their useful or commissioned life as a 'building bank' for other building structures; and materials passports. The UK's Building Research Establishment is a partner in the EU Horizon 2020 Buildings as Materials Banks project, for example. This project, launched in 2015, looks to provide support for research to develop new ideas and ways of embedding circular economy thinking into the built environment. Materials passports are electronic sets of data that describe those characteristics of building materials, products and product systems that enable

value recovery from materials. The resources and materials used in a construction project can be recorded and passed from the supplier, to the construction contractor, the owner and finally to the demolition contractor.

More generally within the construction industry, there is growing interest in circular business models. Guglielmo for example, argued to embrace a change of paradigm in construction, it is crucial to understand the logic behind circular business models' (Arup 2017, webpage). Arup and Bam (2017, p.20) suggested 'to support the transition to the circular economy, governance, regulation and business models will play a crucial role' and argued that 'circular business models would allow the retention of an asset at its highest value over time and support enhancement of natural capital.' More specifically Arup and Bam (2017, p.20) suggested that new business models would allow 'greater control over resources through the value chain so that added value can be identified and captured' and that this in turn will see the 'creation of services that capture valuable products/resources.'

At the same time Arup and Bam (2017, p. 20) argued that 'different circular business models will be required at different stages of a lifecycle of an asset'. In a similar vein van Sante (2017, p. 16) suggested that within the circular economy a range of business models may be identified. Here van Sante (2017, p. 16) identified three models 'on the road to circular construction' namely, the 'sale of product', the 'maintenance model', and the 'service model.' The first model is the 'production and sale of a product', in the second model 'maintenance becomes more important to lengthen the lifespan and manufacturers provide a service and no longer sell a product' and the supplier provides 'more technical services…. such as installation and maintenance with the goal of increasing the lifespan and thus circularity.' In the third model 'ownership and the associated risks remain with the supplier' and 'the user only has access to a service' (van Sante 2017, p. 16). By way of an illustration, van Sante (2017, p. 16) outlines how 'the installer, for example, ensures pleasant interior climate for several years and remains the owner of the system. The idea behind this is that this gives the installer the added incentive to ensure high-grade use in the construction sector.'

 At the company level, in proposing a 'possible construction circular economy model' Bam (2014. webpage), argued that 'rather than selling the customer a product and walking away, we should be looking at providing them with a service contract.' So for example, Phillips, as a provider of lighting, will provide light or lux, and as part of its service contract to provide light, they will provide the light fitting, which the client uses, with a type of material passport to enable it to be tracked over its lifetime.' Further Bam (2014, webpage) suggested 'if the light fitting breaks down, Phillips repair it (by replacing the bulb, part of the electronics, or the whole fitting), to continue its use for as long as practicable' and then 'when light is no longer required, they take back the light fitting for remanufacture.'

Reflections

There is evidence of growing interest in the concept of the circular economy and the development of circular business models within the European construction industry. A number of the major construction companies are emphasising their commitment to the concept of the circular economy and to the principles underpinning it, though some of these commitments are currently aspirational. Looking to the future many companies may well look to follow their aspirations and pursue their commitments as an important

contribution of the wider transition to a more sustainable future. That said, two sets of general issues surrounding the more widespread adoption of the concept of the circular economy within the construction industry merit attention and discussion.

Firstly, it is important to recognise that the development of circular business models and the widespread adoption of the concept of the circular economy within the construction industry will face a number of challenges. Gumilar and Dana (2017, webpage), for example, argued that the adoption of the circular economy within the construction industry will be 'a very challenging task because of the sector's complexity and its various players.' In a similar vein, the Construction Products Association (2016, webpage) noted that, 'work to develop circular economy thinking to date has been focused on short-term consumer goods', questioned 'can this thinking also be applied to buildings and infrastructure that exist for decades if not centuries' and argued 'the challenges for adapting circular economy thinking in construction are likely to be complex.'

More specifically, the Construction Products Association (2016, webpage), identified a range of challenges for the construction industry relating to 'products, buildings and infrastructure', 'recovery of products/materials' and 'business considerations.' In addressing products, building and infrastructure, for example, the Construction Products Association (2016) drew attention to the challenges associated with the long life and the complexity of buildings, the variable lifespan of many of their component parts and changes in specifications and technology over time, which may make some products effectively redundant in the future. In addressing recovery, the Consumer Products Association (2016) suggested that the often low current commercial value of materials and products, the lack of secondary market mechanisms and the lack of effective quality assurance for recycled materials were barriers to the adoption of greater circularity within the construction industry.

In a survey and follow up workshop of over 100 companies within the construction industry, Adams et al (2017) identified a number of key challenges for the adoption of the circular economy across the construction industry. Major challenges included the complexity of buildings; the fragmented supply chain; lack of a market mechanism for recovery; lack of circular economy knowledge; lack of incentives to design for end-of-life products; limited awareness across the supply chain; and lack of interest. The lack of incentives to design for end-of-life issues for construction products was seen as the single most important of these challenges and Adams et al. (2017, p. 20) reported that 'this view was held regardless of the company size or length of experience.' The authors also reported that there 'was a lack of clarity on what the circular economy actually entailed' and that 'the apparent confusion between terms such as reuse and recycling' suggested that 'greater precision is required' (Adams et al. p. 20). This must be seen as a concern for the construction industry, but in par at least, it can be seen to reflect wider views that the 'circular economy seems to be a collection of vague and separate issues from several fields' (Korhonen 2018, p. 37) and that the idea of the circular economy is 'more often celebrated than critically interrogated' (Gregson 2015, p. 218).

In addition to the industry specific challenges outlined above Ritzen and Sandstrom (2017) have identified a number of more general attitudinal, financial, structural, and technological barriers to a transition to a more circular economy. In attitudinal terms, for example, their findings revealed that risk aversion was a prohibitive factor in making

what were seen as disruptive changes to adopt a circular business model. A shift towards a circular model was also perceived to require far reaching changes within companies and to influence all departments and activities. Such changes take both time and investment and where corporate financial systems are focused on rapid returns on investment and cost savings this currently does not encourage long term strategic change. There are also challenges in developing indicators or measures that might help to monitor how a product or a company is progressing towards the circular economy. At the same time corporate finance departments are developing and refining tools to measure the financial costs and benefits of pursuing circular business models.

Secondly, there are wider, fundamental and arguably more contentious issues about the relationship between the emergence of a circular economy, sustainable development and existing economic and political structures. On the one hand, some commentators see the circular economy as 'only a small part of the being sustainable' rather that 'the circular economy is part of how we get there, but not the end goal.' (Sustainablesmartbusiness. com 2015.) However, the vast majority of corporate strategies for sustainability are couched within the idiom of continuing economic growth and business expansion. Bam for example, reported that 'our objective is to continue to grow profitably and capital efficiently' (Bam 2017, p. 5) and suggested that 'mega trends such as sustainability and energy efficiency are creating areas of higher growth' (Bam 2017, p. 7). Such an approach is rooted in the general belief that continuing economic growth will be accompanied by the more efficient use of resources. This trend which is seen as either relative or absolute decoupling (relative decoupling refers to using fewer resources per unit of economic growth while absolute decoupling refers to a total reduction in the use of resources) underpins many conventional definitions of sustainability and the vast majority of current corporate sustainability strategies and programmes.

This position is reflected in some of the general narratives of the benefits of the circular economy. Govindan and Hasanagic (2018,webpage), for example, suggested 'in the last few years, the circular economy has received considerable attention worldwide because it offers an opportunity to optimise and promote sustainable production and consumption through new models based on continuous growth and limitless resources.' In an even more positive vein Glasgow Chamber of Commerce (2016, p. 2) claimed 'the circular economy means enough for everyone forever' and that 'the benefits of the circular economy are endless: reducing dependency on scarce natural resources; increasing their competitiveness; and realising significant financial savings.' Equally pointedly the belief that 'the circular economy would decouple economic growth from resource use' (McKinsey 2015, webpage) can be seen to justify the commitment to both the circular economy and to continuing business expansion and growth despite wider concerns about the continuing consumption of scarce natural resources and the damaging environmental impacts of such growth.

On the other hand, Gregson et al. (2015, p.235) argued that a circular economy 'would require radical transformations to the economic order, including fundamental recasting of manufacture, retail, consumption and property rights.' Such radical changes would extend far beyond the construction sector of the economy. As such, concerns have been expressed that the concept of the circular economy might be captured by corporate interests, and more specifically by corporate capitalism. Valenzuela and Bohm (2017, p. 23), for example, suggested that 'given the all too obvious social and environmental consequences crises associated with out-of–bounds growth capitalism,

the circular economy has been one of the main references for rebuilding and reforming a political economy of sustainable growth.' However, Valenzuela and Bohm (2017, p. 27) further argued that the terms circular economy and sustainability were effectively being 'captured by politic-economic elites claiming that rapid economic growth can be achieved in a way that manages to remain responsible to environment and society.'

Conclusion

A number of the major construction companies within Europe are currently looking to integrate circular economy thinking into their business models and some of them have reported on innovative and experimental initiatives but the widespread and comprehensive translation of such thinking into construction practice is still at an early stage. Ideally the development of the circular economy should involve the whole of the construction supply chain but the main thrust of the initial approaches within the industry within Europe have been dominated by a focus on waste and recycling. More generally, there is growing recognition that if the circular economy is to grow then a range of business models rooted in maintenance and service rather than sales may become an increasingly important feature of the construction industry. That said the widespread adoption of the concept of the circular economy and of circular business models within the construction industry seems likely to face a number of challenges. Indeed, it remains to be seen whether the circular economy can become a workable and realistic business model for the construction industry. More contentiously there are concerns that the major construction companies might effectively capture the concept of the circular economy to justify continuing economic growth while effectively and conveniently ignoring the reality that such growth is essentially unsustainable.

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Italian high-tech manufacturing SMEs in business network: do they perform better?

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Abstract

In year 2009 the Italian Government introduced a new formal agreement between firms, the so-called "contratto di rete" (business network contract), aimed to improve firms' competitiveness and their innovative attitudes by increasing and intensifying the interaction between the firms signing the contract. The focus of the present paper is to explore if medium and high tech manufacturing SME firms participating on the BNCs have really improved their performance - measured through the ROI - and how some key economic variables like tangible and intangible assets, value created and revenues are significant in explaining it. Applying a model-based approach, we also verify the role of the geographical proximity in the definition of BNC firms' productivity. The main findings of the paper support the knowledge based theory and that BNCs are alliance networks based on strategic and calculative relations independently from their geographical proximity, taking advantage of network capital resources.

Keywords: Business Network Contract, Medium-High Tech Sector, ROI, SMEs.

Introduction

Business Network Contract (BNC) is a medium-term agreement that can be signed between firms, regardless of their national geographical localization. BNC have to include specific contents, like the definition of their strategic and operative program, the specification of the governance of the network and the definition of some performance indicators aimed to verify the ability in achieving the network objectives.

BNC seems to be perceived by firms as a winning instrument and it widespreads rapidly in Italy, with more than 3,985 contracts signed between 2010 and September 2017, involving more than 20,100 firms. Nevertheless, there is few empirical analysis devoted to investigate the driving factors of the - increasing - performance of the firms involved in BNC.

In the present paper, we focus our attention only on small medium-high technology firms, because these are of particular interest for researcher and policy makers, given their potential innovative dynamic that can regenerate the Italian industrial gap. Moreover, the BNC are introduced specifically to improve competitiveness and innovation of the firms.

According to Pavitt classification (Pavitt, 1884), we consider as medium-high tech firms those included in electronically, optical, chemical, pharmaceutical and mechanical sectors.

In literature we can find many papers devoted to the analysis of firms' performance, starting from different theories. The 'Resource based' theory views firms with superior systems and structures as more profitable because of their efficient ability to use internal resources. Instead, the 'Knowledge based' theory considers knowledge the most strategically resource to create and sustain competitive advantage, by adapting, integrating and reshaping the internal organization skills, the resources and the functional competences, to match the requirement of a changing environment (Teece, 1996).

It is undeniable that the presence of resources and, in particular, of adequate investments (tangible and intangible) is essential to ensure good business performance. However, the ability to develop 'knowledge' and 'skills' through interaction with other firms has been proven to be another key factor, especially for SMEs, to ensure a competitive advantage.

Therefore, inter-firms networks have been studied for their ability to guarantee higher innovation and performance, distinguishing two type of resources: the 'social capital', based on social relations, and the 'network capital', based on strategic and calculative relations (Huggins and Johnston, 2010).

The BNCs studied in this paper are 'alliance networks' based on stable and collaborative relationships between firms, aimed at improving firms' competitiveness and their innovative attitudes. This type of inter-firm relationship is coherent with most of the current literature on networks, focusing on 'repeated' and 'enduring' or 'sustained' interactions, and is considered an important feature of the network development (Podonly and Page, 1998).

Moreover, BNC is an instrument able to connect firms non-locally. In literature, the use of alliances with regional external knowledge partners, is seen, by some authors (Boschma and Frenken, 2006; Huggins and Johnston, 2010) a point of strength to achieve higher innovation. Differently from industrial districts, BNC aims to aggregate a few number of firms on a specific program of activities, independently from their geographical proximity.

In Italy, BNC has recorded a rapid diffusion, by supporting its utility for businesses. However, it is interesting to see if it really ensures a better performance of the firms, and which network features, in terms of spatial proximity, network size, sectors involved, can influence their productivity.

Overall, the present paper addresses the following two main issues:
• which economic variables positively influence performance after getting in a BNC;
• which network characteristics positively influence the productivity after getting in a BNC.

The first question aims at understanding the economic reasons of a better performance (in terms of ROI) of networked firms, which could depend by many

factors, as higher investments, greater internal efficiency and productivity, better financial structure, etc.

The second question has the purpose to understand if and how some structural characteristics of the networks (size, sectors involved, proximity) influence the productivity of the firms, allowing identifying a "benchmark structure" for the success of the aggregation. Therefore, we can formulate the following assumptions:

A1: A better performance (in terms of ROI) after signing the BNC is positively affected by one or more of the following economic variables:
Investments (tangible and intangible)
Productivity (value added per-capita)
Financial structure

A2: Network capital (in terms of VA per-capita) after signing the BNC is positively influenced by one or more of the following network characteristics:
Network resources
Spatial proximity
Type of aggregation (mono-multi sectors)
Network size

Starting from a review of the relevant literature, we initially develop a framework to characterize inter-firm relevant variables for explaining the performance (second section), by also reviewing the role of space, regional proximity and size. The third Section gives some details of our methodological approach and introduces the used dataset. Our empirical results are presented in the fourth Section. Finally, some conclusions summarize the key findings of our analysis in terms of performance and productivity of BNC firms of medium and high-tech SMEs.

Review of national and international literature

Firm networks have been defined (Hanna and Walsh, 2008) as a complex pattern of formal and informal linkages between individuals, businesses and third parties as brokers or not-for-profit agencies. Economic literature on inter-firm relationships highlights on the synergies arising from the cooperation among interconnected firms and describes the different peculiarity of networking. Networks have been recognized as an important asset to guarantee a competitive advantage. Worldwide studies have shown that the participation to a network will influence the viability and development paths of the member firms (Whittington et al 2009; Powell et al 1996; Gulati et al 2000).

Inter-firm relationships were recognized as a positive factor of firms' performance (Zott and Amit, 2007) and innovation (Capaldo, 2007). Nevertheless, many authors (Kingsley and Klain, 1998; Hanna and Walsh, 2008) found evidence of difficulties for SMEs in establishing successful cooperation, suggesting the use of brokers or other tools. At the same time, it was argued that SMEs might benefit from the networks, by overcoming their isolation, through the exchange of information and ideas with external partners.

Powell (1990) considers small-firms business networks a new emerging organizational form, in which aggregation is determined by reasons different from spatial proximity or homogenous social community (as in the industrial districts). In the networks, members are neither homogenous nor fungible and rather than developing spontaneously, they are intentional created. Moreover, networking is seen a way for SMEs to compete globally (Mort and Weerawardena, 2006).

Laursen and Salter (2005) found out that many innovative firms have changed their way to search for new ideas, by adopting open search strategies that involve the use of a wide range of external actors and sources, that help them achieving and sustaining innovation.

Starting from the knowledge-based theory, Huggins and Johnston (2010) observed that firms investing more in inter-firm and external knowledge networks, achieve higher levels of innovation, and conclude that the link between a dynamic inter-firm network environment and innovation provides an alternative thesis to that advocating the advantage of network stability.

Few studies focused specifically on network firms' performance with respect to the spatial distribution of the BN firms. About the importance of spatial variables, several studies claim that firms in a cluster benefit form knowledge externalities because their geographical proximity facilitates (tacit) knowledge sharing while, on the contrary, other studies claim the role of geographical proximity (in a pattern of knowledge exchange) tend to be overemphasized because extra cluster linkage are important for innovation.

Oerlemans and Meeus (2005) for example, underline the importance of proximity for innovative outcomes, concluding that intraregional relations with buyers and suppliers are conducive for firm performance.

Instead, Romijn and Albu (2002) observed (on a sample of South East England electronic firms) that the innovative performance of small high-tech firms relates to their external networking activities, finding not support to geographical proximity benefits.

In particular, Boschma and Ter Wal (2007) affirm that 'having an absorptive capacity seems to raise only indirectly, through non-local relationships, the innovative performance of firms, concluding that being co-located is not enough, because knowledge externalities in a district are not in the air' (cfr. pp.196). This interesting consideration led the authors to consider the 'cognitive proximity' a very important feature and firms with a high absorptive capacity can also be non-locally connected.

In Italy, industrial districts and other strategic networks have been seen as an instrument to improve competitiveness through cross-firms knowledge diffusion (Lorenzoni G., 2010; Camuffo and Grandinetti, 2011; Trequattrini, 2012) and traditionally, Italian industrial model is strongly based on networks. Distinctive feature of industrial districts is that the production is achieved by a group of relatively independent local firms that are specialized in one or more segment of the supply chain. More recently, attention is shift from industrial district to business networks and, in particular, to BNC. These are able to ensure a strategic vision able to

generate competitive advantages (Grandinetti, 2014; Tunisini, 2015, Brino et al, 2015).

Some theoretical and empirical studies tried to explain the reasons underlying the Italian firms' aggregation. Aureli et al (2011) classified the strategic goals of networked companies as defensive, proactive, consolidating, or in their combination. In particular, Italian SMEs look at the network as an opportunity to increase their innovation and competitiveness. The empirical analysis on 25 contracts carried out by Aureli et al (2011) revealed that the most common agreements are those involving research and development (72%) and marketing activities (72%), followed by production agreements (68%) aiming to increase productivity and efficiency by implementing joint projects.

Ciambotti et al (2013) analyze, through some case studies, the elements necessary to a correct operation of inter-company relations in business networks, with particular attention to the manufacturing sector, providing the basis for an effective SMEs BNC expansion.

Tunisini et al (2013, p.120) analyze thoroughly the relationships that arise between BNC companies, and conclude that it is not the 'contract' by itself that allows a better performance but the 'communion of intent that provides substance to a project that then meets in the contractual form a fertile ground where it can express itself to the best'.

Massari et al (2015, p. 144) made semi-structured interviews with 4 case studies and affirmed that BNC is an effective tool to improve the competitive performance of the involved firms, turning them into a "real player" in the market.

Attention on BNCs was also grown because of their ability to improve territorial development. On this regard Capuano (2015) identifies in the network contract "a regional policy instrument aimed, in addition to the growth of the businesses, to the reduction of territorial imbalances". Analyzing 1,358 network contracts (signed until 31/12/2014) the author notes that most of the contracts involve companies operating in the same region and that the territorial variable is crucial to determine the success or failure of a company and the decision to activate a new BNC.

It is an open question if the management model of BNC is alternative or not to other territorial aggregation, like the industrial districts.

If the strategic, organizational and territorial elements of the Italian BNC have been deepening analyzed, there are still very few contributions to the analysis of the performance of firms involved in BNC. Intesa Sanpaolo-Mediocredito Italiano – Observatory made on 2014 a quantitative analysis of BNC, with the aim to verify the effects of network contracts on the 'income performance of companies entering the network in 2011'. This research highlighted the absence of a positive growth of the companies involved in the network in the short term. This result is likely to reflect the kind of contract objectives, often defined on medium and long-term strategies, such as innovation and internationalization.

Data used in the analysis

Data used in the present paper were extracted from the Business Register of the Italian Chambers of Commerce for the Network contracts signed in 2010-2012 by the manufacturing firms, for a total of 700 small-medium capital companies. We did not consider companies that at the time of the signature of the contract had less than 3 years of life.

After that, we matched our firms with those of the AIDA (Analisi Informatizzata delle Aziende Italiane) database. AIDA is a database containing financial, personal and commercial information on equity companies operating in Italy and is based on the official financial statements deposited in the Italian Chambers of Commerce. Therefore, from AIDA we extract additional information, as Revenue, Value Added per Capita, ROI (in percentage of revenue), Tangibles and Intangibles Assets. In this way, we were able to obtain a unique record of data that contains all the information collected in the different data sources. All the variables were observed from 2008 to 2015. In this way we could monitor the firms before and after signing the BNC, and have an overview of the trend of the performance of the BN firms. Most of the contracts were signed in 2012.

According to Pavitt taxonomy (1984), we identify the four sectors:

1. Dominated by suppliers, as textile, food, agriculture;
2. Scale intensive, as steel and consumer goods;
3. Specialized supplier, as mechanical engineering and machinery manufacturing;
4. Sciences based, as electronics and pharmaceutical.

and the firms were classified in accordance to them. In our analysis, we focus only on the high-tech firms, identified by sectors 3 and 4 (i.e. specialized suppliers and sciences based).

We did not consider companies in liquidation and companies with missing financial data. Starting from around 250 high-tech companies our final dataset was composed by 149 companies.

Moreover, in line with the research questions highlighted in the previous sections, we built some structural control variables, regarding the size of the network, the geographical proximity of the firms in the BN and the mono/multi sectorial composition of the BN.

The Network size variable is defined through a categorical indicators, based on the number of firms included in the BN: small (1-3 firms), medium (4-9 firms), large (> 9 firms).

Particular attention is devoted to the definition of the geographical distance.
BNC is an instrument able to connect firms non-locally and this can be considered a point of strength to achieve higher innovation. Differently from industrial districts, BNC aims to aggregate a few number of firms on a specific program of activities, independently from their geographical proximity. Therefore, we introduce a variable able to measure the geographical distribution inside the BNC.

The geographical distance is defined according to the following classification: 1) network firms located in the same province; 2) network firms located in the same region; 3) network firms located in adjacent regions; 4) network firms located in different regions. Finally, we classify BN as mono- or multisectorial, through a binary 0 - 1 variable.

Descriptive analysis and model based methodology

The main aim of our paper is twice: the analysis of the performance of BN firms and the identification of the most important structural determinants affecting the productivity of them. To this end, we performed different empirical analysis, following distinctive approaches. First of all, we make an introductive descriptive analysis of some key variables explaining the performance and the productivity of BNC firms. These were analyzed in terms of before-after entering in the BN. However, to avoid misspecifications, we match our results with those observed over some benchmarking manufacturing firms, given by Unioncamere-Mediobanca reports. In this way, we were able to have a dynamic overview of some key variables of the BNC firms.

However, the main aim of the present paper is to explain the performance and the productivity of BNC firms, "after" getting into the contract. Therefore, our model-based analysis is limited to the period 2012-2015.

The first estimated model will explain the performance – given by ROI – of the BNC firms with respect to different explanatory variables, according to standard literature. To this end, we apply a balanced panel regression model with fixed (time) effects:

$$Y_{it} = \beta_{0t} + \beta_1 X_{it}^1 + ... + \beta_k X_{it}^k + \varepsilon_{it} \quad i = 1,...,n \quad t = 2012,...,2015 \qquad (1)$$

where the dependent variable Y_{it} is the ROI and the explanatory variables X_{it}^k: Employees, Value Added per Capita, Debt equity, Liquidity, Intangible and Tangible Investments. The time stationarity of the variables over the analyzed period suggests the use of variables in level. However, to overcome problems in terms of dimensionality of the estimated coefficients and of heteroschedasticity, Employees, VA per Capita and Investments were rescaled with the log operator.

When units (in our case firms) are observed at several points in time, the panel data model is the more appropriate way to estimate the relationship between dependent and explanatory variables. The use of the panel model allowed to have more extended information set than standard regression, with a total of 596 observations (149 firms over 4 years), giving more efficient estimation (Baltagi, 2008). Moreover, the intercept term $_{0t}$ in equation (1) can be different for each time period and the fixed-effect permits to control stable characteristics of the firms whether they are measured or not.

A second regression is performed to see how the productivity of the BNC firms is influenced by some structural characteristics: network size (NS), spatial distance (SD), mono-multi sectorial (MS) and global investments (INV). The productivity is expressed through the Value Added per Capita (VA). In this case, we estimate a

standard regression, because most of the explanatory variables are constant over the period 2012-2015:

$$VA_i = \beta_0 + \beta_1 NS_i + \beta_2 SD_i + \beta_3 MS_i + \beta_4 INV_i + \varepsilon_i \quad i = 1,...,n \qquad (2)$$

The VA and INV variables are given in terms of their mean over the observed time interval.

This second regression will highlight how the localization of the firms in the BN, the dimension of the BN and the mono-multi sectorial composition will influence the productivity, allowing to identify a "benchmark structure" for the success of the aggregation.

The estimation output of the two models, together with the descriptive statistics, is reported in the next section.

Empirical analysis

Before running our regression models we analyze the data of our sample over the two different periods: before (2008-2011) and after getting in the network (2012-2015).

The first table shows the ROI (computed on average over the four years) of about 560 firms allocated in the four Pavitt sectors. Only sectors 3 and 4 are considered high tech sectors and included in our final estimation.

Table 1 - ROI before and after the BNC

Pavitt Sectors	2008-2011	2012-2015	Difference
Dominated by suppliers	7,3	6,9	-0,4
Scale intensive	6,9	7,3	0,3
Specialized	6,6	8,3	1,7
Science based	7,6	8,3	0,7

On average ROI improves after signing the BNC, with more evidence for the high-tech firms. However, the before-after comparison should be made carefully, because the ROI should be compared with that of non BN firms. Unfortunately, the unavailability of such matching data, forces us to follow alternative analysis. We consider the survey made by Unioncamere-Mediobanca (2016) (hereafter UM) that covers the universe of medium-sized Italian manufacturing firms with 50-499 employees []. These firms can be seen as a benchmark, because of their outstanding turnover, that historically was always higher than that of SMEs. UM Report asserts that only starting from 2014 we can observe a recovery, and the ROI, computed over almost 1700 firms, has increased between the two time intervals, about 0.8. Therefore, we can state with confidence that our BNC high-tech firms have improved their ROI after signing the contract, not only for the presence of an overall positive trend, but also for their inclusion in the BN.

Table 2 analyzes the ROI with respect to the geographical distance between the firms composing the BN. The performance has increased more significantly in network firms belonging in different regions, validating the idea that regional external knowledge triggers innovation.

Table 2 - ROI and geographical distance

Spatial distance	2008-2011	2012-2015	Difference
Same Province	7.4	6.2	-1.2
Same Region	6.7	7.7	1.0
Contiguous Regions	6.8	9.5	2.7
Different Regions	7.0	10.2	3.2

Looking at the tangible and intangible assets before and after the BNC, we have that both kind of investments decreased in the 'after' BN period.

Surprisingly, the average value of the investments after getting in the networks is lower than before, showing a limited ability of the BNC instruments to be driver of new tangible and intangible investments. However, this evidence is in line with UM data that show how tangible investments decreased about 8%. Figure 1 shows the two series over the entire analyzed period.

Figure 1 Tangible and Intangible assets in 2008-2015
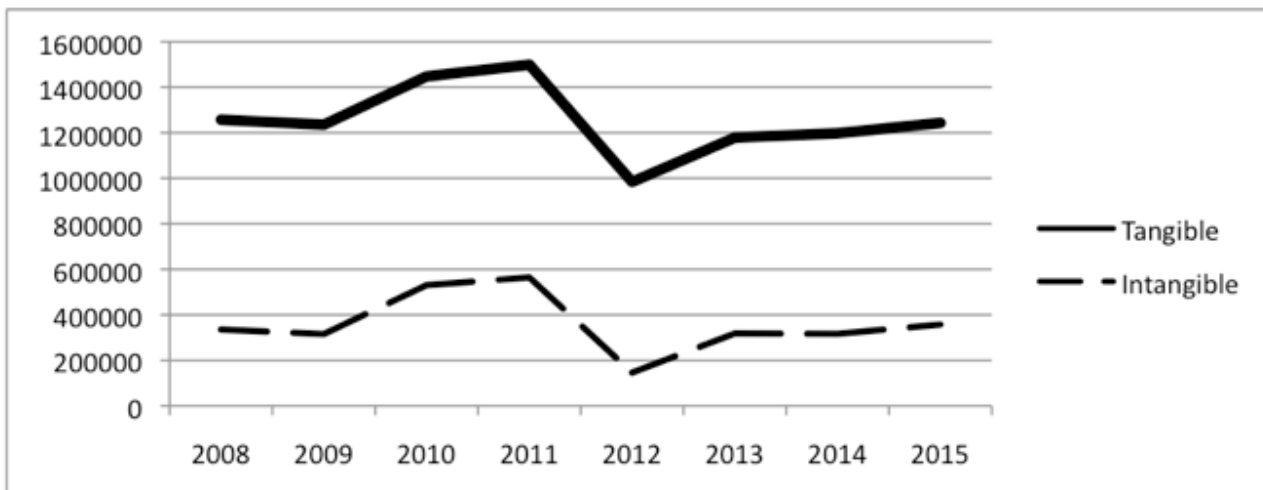
Although the two series are - in level - lower in the 'after' period 2012 – 2015, there is evidence of a trend inversion in 2012, when the investments start again to growth.

Moreover, the analysis of the BNC firms' performance is carried out through the estimation of a balanced panel regression model, where the dependent variable ROI

24

(i.e. the performance) is expressed as a function of investments (intangible and tangible), productivity and financial variables (liquidity and Debt/equity ratio). The output of the panel regression is reported in Table 3. The aim of this model-based analysis is to better understand which are the driving factors of the BNC performance.

The key findings of the panel regression show that ROI is influenced by the Value added per capita, the Tangible and Intangible assets, and the Employees. These results confirm the assumption that strategic or stable alliances are able to produce "network capital".

Network capital allows a higher productivity, measured by value added per capita, in coherence with the "knowledge based view". Moreover, resources (i.e. Tangible and Intangible assets) confirm their importance in terms of firms' development, also in absence of a significant increase of them in the analyzed period. As a consequence, the "knowledge" factors seem to prevail, in terms of a better performance.

It is interesting to note that ROI is not influenced by financial factors, like Debt /Equity ratio and liquidity. Nevertheless, many banks are evaluating the opportunity to introduce a new rating method for BNC that, in the long run, could ensure better financial conditions. Finally, the size of the firms, expressed through the number of employees, has a positive impact on the performance.

Table 3 - Estimated panel model for ROI

Starting from the previous results, where the value added per-capita is the most important driver of the performance of BNC firms, we apply a second regression to look deeper on the driving characteristics of the productivity, in function of the following regressors: i) spatial distance, ii) network size, iii) sectors of the firms and iv) total investments (Table 4).

BNCs between firms located in different regions ensure a higher value added than co-located firms. This result supports theories advocating "being co-located is not enough" and confirms that aggregation is determined by reasons different from spatial proximity or homogenous social community, but is based more on the common objectives defined between the involved firms (Boschma and Ter Wal, 2007).

Although network size is not significant, it is positively correlated with the distance. This means that the larger the networks, the farther the firms are. In coherence with Huggins (2001), this means that firm size plays an important role for the knowledge networks pattern and network dynamism is an important feature of innovation and a better performance.

Table 4 - Estimated model for the productivity

	Coefficient (standard error)	p - value
Employees	0.7264 # (0.4217)	0.0844
VA pro Capite	7.6759 *** (0.6998)	<2.2e-16
Debt equity	0.0481 (0.0709)	0.4977
Liquidity	0.0013 (0.0009)	0.1484
Immaterial Inv	0.2469** (0.0914)	0.0071
Material Inv	1.6499*** (0.2119)	3.124e-14

In our regression, we have that networks composed by firms from different sectors have a higher productivity, in terms of value added. This is in line with standard literature, that affirms that decentralized networks (where information and knowledge are horizontally distributed) ensure better productivity.

Finally, value added per capita is positively influenced by new investments and this evidence is coherent with the resource-based view, although, the average investments in 2012-2015 are lower than in 2008-2011.

Our empirical analysis highlights that network contracts are an important instrument to increase the value added trough 'knowledge sharing'. Therefore, industrial policy should encourage and stimulate the participation of SMEs into multi-sector BNCs, intentionally construct to improve firms' competitiveness.

Conclusions

In the present paper we analyzed the Italian high-tech SME manufacturing firms that signed a BNC, in terms of their performance (measured through the ROI) and their productivity (measured through the VA per Capita). Our results highlight that the Italian business network contract is an instrument able to increase firms' competitiveness by intensifying the interaction between the firms and allowing knowledge sharing, also between geographically distant firms. In fact, the majority of the high-tech SME firms in our sample has improved their performance by participating on the BNCs.

According to the first research question, the economic variables affecting positively the performance (after signing the BNC) are mainly the Productivity (value added per-capita) and the Investments (tangible and intangible). In particular, our empirical results show that 'internal and external efficiency' given by knowledge sharing practices will positively influence BN firms' productivity. This result is consistent with the literature, which recognize inter-firm relationships as a positive factor of firms' performance because of the synergies arising from the cooperation among interconnected firms. Performance is also positively influenced by firms' tangible and intangible investments. Nevertheless, the absence of fiscal and tax incentives for investments, together with a cautious post-crisis expectation, led to relatively small asset values during the analyzed period 2012-2015, although a trend inversion is present in the recent years. This result is consistent with the resource based view theory, which recognize to an increase of resources a positive influence of firms' performance. Nevertheless, in our sample, the driver of a better performance seems to be based more on knowledge and intangible factors rather than to an increase of Investments.

The non-significance of the financial variables suggests the introduction of policies in favor of networking companies with connected benefits, to strengthen the investments. In particular, the Financial Institutions should consider the creation of a network rating that aim to allow a better and easier financial support for networked firms to increase investments.

In the second research question, the non-economic variables positively influencing the network productivity are spatial distance, type of aggregation and, again, the invested resources.

Looking at the spatial dimension, our results support the idea that BNC firms can benefit of regionally external knowledge of the partners, to achieve higher innovation and productivity. Applying a model-based approach, we verified the role of the geographical proximity in the definition of BNC firms' productivity. The main findings of the paper support the knowledge based theory and that BNCs are alliance networks based on strategic and calculative relations, independently from their geographical proximity, taking advantage of network capital resources.

Moreover, BNC with firms from different sectors showed a higher value added. This is in line with the literature affirming that the "value" of knowledge is higher when horizontally distributed. Finally, it is not surprising that value added per capita is positively influenced by new investments, in line with the cited resource based approach,. Our results suggest that larger networks, which operate in high technology sectors located in different sector areas, have more chances to be successful in terms of productivity.

All the previous results may have important implications in the application of industrial policies of SMEs, suggesting that the Italian Government is going in the right direction in supporting BNC.

The main limitation of our study is given by the reduced analyzed time period, as the BNCs were introduced in Italy only in the 2010. However, the benefits for the firms entering in the networks, will be evident after many years. Therefore, we need to wait some more years, to capture more properly the dynamic of the performance of BN

firms. Furthermore, many missing values in the accounting variables analyzed in the paper, reduced drastically the starting available dataset, by limiting our empirical results. We hope in the future to fill up this information hole through the access to other datasets. Future research directions aim, therefore, to extend the analysis on a wider sample of firms and on a larger observation period.

Endnotes

1. The data of Unioncamere-Mediobanca stop at 2014 and consider firms with 50-499 employees and 15-330 mln€ of revenue.

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Quantitative findings on post-marketing surveillance practices of IVD industry in Europe

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Abstract

Purpose – The aim of this paper is to investigate safety oriented post-marketing surveillance practices of the In-Vitro-Diagnostic-companies in Europe, indicating industries overall attitude and practices towards post-marketing surveillance standardisation, examines the determinants influencing IVD companies' behaviour towards it, and finally critically discusses underlying managerial implications of the results.

Design/methodology/approach – For investigating company's attitude towards post-marketing surveillance practices, a rating scale Rasch model is used. Subsequently, structural equation modelling is used for the critical examination of IVD companies post-marketing surveillance standardisation behaviour and its relationships to the development of safe and efficient products. Furthermore, an extensive literature research is carried out for the provision of theoretical foundations.

Findings – The results revealed most IVD companies attitude towards post-marketing surveillance practices are limited. Furthermore, many IVD companies do not use any standardised specific post-marketing surveillance strategies and tools to helping in collecting, analysing, scrutinising and sharing information within a given market or country. Confusion caused by selective application of regulations and standards negatively impacts validity of post-marketing surveillance practices. The results reveal that IVD-companies do not plan and manage their post-marketing surveillance activities according to their favouring and obligating determinants. This paper categorises these favouring reasons pulling towards the use of a standardised post-marketing surveillance approach and obligating factors pushing towards it.

Research limitations/implications – This research provides marketing practitioners and researchers with an overview of the determinants influencing post-marketing surveillance of IVD-companies in the European market. Furthermore, the study applies transcends descriptive analysis for the identification of IVD companies post-marketing surveillance behavioural issues and to recommend post-marketing surveillance approaches regarding enhancement of efficacy and safety of their products.

Originality/value – This paper provides empirical findings on post-marketing surveillance practices by the use of in-depth quantitative analysis of a sufficient sample of IVD companies. The study's findings reinforce the idea of a strategic post-marketing surveillance practice with standardised tactics as a manifold construct to enhance safety and effectiveness of IVD-products. In this, the paper provides explicit conclusions in the post-marketing surveillance practice and categorises factors according to their significance for the use of a standardised approach. Furthermore, valuable prescriptions of post-marketing surveillance tactics, based on the findings, are provided.

Keywords – Post-marketing surveillance, IVD industry, marketing strategy, marketing planning

Introduction

Post-marketing surveillance practices of the IVD industry have not yet been exhaustively researched and measured by in-depth statistical analysis, as both post-marketing surveillance practices and the measurement of the relative weight of each of the determinants affecting the practices still have to be investigated and knowledge about these issues has to be enhanced. This research makes a significant step towards eliminating these knowledge gaps and contributes to knowledge by providing a theoretical understanding about this subject and pointing out its managerial implications. In this, regulatory affairs and marketing managers balance benefits and risks of IVD products every day (Siekmeier & Wetzel, 2013). The Directive 98/79/EC and the Ordinance of Medical Device Vigilance Systems (Heinz, 2009) obligate companies to carry out post-marketing surveillance of IVD products and to systematically examine benefits and risks gained from products on the market (Bremond & Plebani, 2001). The implementation of preventive and corrective actions is based on the benefits and risks assessed, whereas the determinants influencing the 'experiences gained' are vaguely defined, making post-marketing surveillance standardisation a difficult task. Furthermore, managers think that the review of the experience gained provides robust evidence with regard to benefits and risks (Howes, 2007), whereas other sources also suggest the use of standardised practices and controls to bring robust evidence (Armbruster, 2009). Post-marketing surveillance necessitates a common approach for ensuring the safety and efficiency of IVD products, encompassing standardised post-marketing surveillance practices to be included within the companies' overall quality management approach (McNerney, Sollis, & Peeling, 2014; Vergo & Benson, 2013; Zippel & Bohnet-Joschko, 2016). This is supported by Philipson (2007), pointing out that standardised post-marketing surveillance practices enhance safety and efficiency for the regulatory approval of IVD products. The simple surveillance of manufacturers' handling of incidents related to their products has often only limited utility to fully assess safe and efficient use, as incident handling may be too short to show long-term experiences (Manthei, Hathaway, & Richards, 2010). Schneeweiss (2007) claims that monitoring of incidents underrepresents or excludes long-term effects of IVD products. This is supported by Chowdhury (2013), stating that in terms of post-marketing surveillance practices, most companies focus merely on incident monitoring and reporting, leaving other strategies and tools such as vigilance reporting and customer complaint handling completely out of sight. The EU Directive for In Vitro Diagnostic Medical Devices demands in Annex III proactive post-marketing surveillance practices, represented by a "systematic procedure whereby manufacturers review various sources of information to gather data" (Lim, 2010, p. 58). According to Siekmeier and Wetzel (2013), such a systematic and standardised procedure enables the company much more to proactively collect data and, in comparison, detect infrequent complications, and to implement appropriate actions to increase the safety and efficiency of products. Earlier, companies merely focused on the fulfilment of regulatory hurdles in order to bring IVD products to market. As the European IVD technology industry faces enormous changes because of financial downturn and changes in regulatory and reimbursement processes, the standardisation of post-marketing surveillance practices not only increases the products' safety, it also reduces the number of incidents and helps to develop sophisticated tools to determine and satisfy customers' needs, another determinant influencing post-marketing surveillance (Howes, 2007). Several authors stipulate that possible sources of information including patient follow-up of clinical trials, scientific papers and reports, customers' surveys and communication reports by regulatory bodies are tools to be implemented within post-marketing surveillance practices (Chowdhury, 2013; Dumbrique, 2010; Ershova, 2011). For example, Zippel and Bohnet-Joschko (2016), in a milestone paper,

argued that the standardisation of post-marketing surveillance practices offers manufacturers of IVD products the chance to monitor their products' post-marketing and post-production performance in a proactive and systematic manner, in line with the applicable IVD laws and regulations. More specifically, the standardisation of these practices enables manufactures to ensure the fulfilment of their responsibilities in the post-market phase, including, particularly, to systematically review experiences gained on the market, to implement corrective actions, to report incidents, to report vigilance events, to carry out field safety corrective actions (FSCA), to conduct withdrawals and recalls and to update post-marketing surveillance standards (Hancher & Foldes, 2013; Tamura & Kutsumi, 2014; Tobin, 2014). The determinants influencing post-marketing surveillance practices are expanded by Chowdhury (2013), noting that performing internal audits for ensuring high safety and performance levels of IVD products and technical file lifecycle management should be included as a separate step within any standardised post-marketing surveillance practice. Followers of this thought argue that IVD manufacturers should use the contents of audits as a basis for adjusting their post-marketing surveillance management in order to comply with regulatory and marketing requirements. In this, regulatory affairs and marketing managers should stipulate a logical and coherent approach, as the benefits which an IVD manufacturer could gain through a standardised post-marketing surveillance approach include exceeding customers' expectations, using economics of scale and increasing the safety and effectiveness of devices. A coherent post-marketing surveillance practice also enables the companies to automatize the dissemination of information and reports, e. g., to find out if similar product lines within the company may be affected by an observed issue (Siekmeier & Wetzel, 2013). Reality proves that manufacturers show only limited interest in conducting standardised post-marketing surveillance practices. Particularly because of the absence of a standardised approach, advantages are unknown, deficiencies in knowledge exist and rout causes of safety deficiencies remain unclear (Huang, Moon, & Segal, 2014). This is confirmed by Siekmeier and Wetzel (2013), outlining that until today only little research on a standardised post-marketing surveillance practice has been published. The development of a standardised practice is favoured by the fact that the IVD industry is highly homogenous, particularly in terms of the product type, the product technology, the customers' target market and the clinical fields where the products are sold and used (Braga & Panteghini, 2014; Panteghini, 2009). This research is an empirical investigation of safety and efficiency oriented post-marketing surveillance practices of IVD companies in Europe, as up until now only very little research on the investigation of IVD companies has been published (Mehta, 2008). This paper adds valuable insights into the determinants influencing IVD companies' behaviour towards post-marketing surveillance practices and then categorises practical issues and determinants relating to these practices. This paper researches in particular the standardised approaches developed and used within the Europe-based IVD manufacturers in relation to different post-marketing surveillance determinants described in literature. The term "Europe-based IVD manufacturers" in the context of this research refers to enterprises intending to manufacture products for the in vitro collection, preparation and examination of specimens taken from the human body, solely or principally to provide information for diagnostic, monitoring or compatibility purposes (Richmond, 2008). Furthermore, the companies selected for this research have been operating in Europe for over five years, exporting their IVD products within European market. The originality of this research lies in the fact that it applies advanced statistical modelling, corroborating past research through in-depth statistical analysis; and in its provision of objective insights into determinants that influence the safety-oriented post-marketing surveillance practices of the IVD manufacturers in Europe in a standardised way. In this, the research categorised the determinants influencing post-marketing

surveillance practices, incorporating them within a standardised approach and highlighting the managerial implications.

Theoretical background

Post-marketing surveillance

In their effort to collect, analyse and share information concerning issues about the IVD products sold, IVD companies should establish principal mechanisms for providing feedback about medical devices in a standardised and systematic way (EC/98/79, 1998). In the field of medical device manufacturing, when an enterprise decides to market IVD products, fundamental decisions about marketing surveillance mechanisms have to be made, as the most important part of such an approach is due to the requirement for IVD manufacturers to introduce a standardised procedure for reviewing post-production device experiences (EC/98/79, 1998; MEDDEV/2.12/2, 2012). This mechanism is commonly referred to as post-marketing surveillance approach, including clinical market follow-up & and market vigilance, with its analysis of information, implementation of corrective and preventive actions, dissemination of findings and change management (Giroud, 2004). However, literature quoting practical evidence outlines that enterprises see post-marketing surveillance practices as a bureaucratic burden which the enterprise takes upon itself for the sole reason of fulfilling mandatory regulatory requirements, in order to freely produce, distribute and market IVD products (Siekmeier & Wetzel, 2013). Lim (2010) argues that the basis for a post-marketing surveillance approach should rather be the wish to support fast market and technical progress by means of a standardised procedure for favouring, facilitating and guaranteeing the safe and effective manufacturing of IVD products. The author goes further, stating that determinants influencing post-marketing surveillance attitudes have to be identified, as researching the experiences gained by IVD enterprises helps to develop a standardised approach and helps to put post-marketing surveillance activities into practice (Lim, 2010). In this, Mechanic (2006) suggests the major restructuring and standardisation of a post-marketing surveillance approach, including the implementation of the IVD approval process within such an approach. In the same line, Pokorski (2013) states that IVD manufactures should be required to implement IVD approval within the post-marketing surveillance approach and that it is an established tool, integrated within the overarching business-strategy, to enhance product safety even though further optimisation is possible. The author goes further, critically adding that it is a must to identify the determinants related to post-marketing surveillance practices, in order to restructure and standardise this approach. This view is supported by Castle and Ries (2009, p. 68), emphasising the fact that "despite an avowed emphasis on post-marketing controls in device regulations, it would seem that post-marketing surveillance has not changed much in practice for [...] manufacturers". In order to be effective, this practice needs to be standardised and efficient methods have to be established to collect and share information on the safety, quality and efficiency of IVD devices, once they have been marketed (Castle & Ries, 2009). Recently, regulating bodies and health authorities began to address this problem in an initiative for the improvement of IVD companies' post-marketing surveillance attitude (EMA, 2012; FDA, 2006; Manthei et al., 2010). Furthermore, many companies have limited knowledge concerning effective and standardised post-marketing surveillance practices, resulting in a limited attitude towards the safety- and efficiency-oriented execution of this practice (Boy et al., 2011). This is supported by Castle and Ries (2009, p. 72), outlining that because of the limited effort and knowledge, "the failure to develop an adequate system of post-marketing surveillance is more critical". The importance of an interaction method enabling the identification of direct

and indirect influences of determinants pertaining to a safety- and efficiency-oriented post-marketing surveillance approach is highlighted (Boy et al., 2011; Braga & Panteghini, 2014; Mannonen & Riikonen, 2006; McNerney et al., 2014). Steffen (2005) states that, furthermore, dissimilarities in the definition of post-marketing surveillance confuse IVD manufacturers and make it difficult for them to gain information about the safety, quality and performance of their products and to establish a standardised approach. However, as Siekmeier and Lütz (2007) conclude, the situation, particularly in recent years, has changed, A growing number of IVD manufacturers suggest that there might be many potential gains to be obtained by the application of a standardised post-marketing surveillance approach. In addition to this, Hogarth, Barton, and Melzer (2010) emphasise that, therefore, the general requirements, both from a regulatory and a manufacturers' perspective, serve as a starting point for researching determinants pertaining to post-marketing surveillance practices:

- IVD manufacturers proactively carry out post-marketing surveillance practices in order to gain information about the quality, safety and effectiveness of their products,
- IVD manufacturers establish a standardised practice to enhance IVD products' performance,
- IVD manufacturers collect, analyse, prioritise and manage information relating to the performance of their products.

In this, the main determinant is the establishment of a standardised procedure to review experiences gained from products in the post-production phase. On the other hand, the Directive 98/79/EC and the Ordinance of Medical Device Vigilance Systems require the post-marketing surveillance practices to be in direct proportion to the risk associated with the product. This is confirmed by the Global Harmonisation Task Force, studying the requirements for post-marketing surveillance practices of IVD manufacturers, critically claiming that "Notified Bodies may request […] performance of the device be carried out after placing the device on the European market" (GHTF, 2005 p. 10). They further claim that the performance of the IVD product is associated with its risk and that, therefore, its assessment should be carried out by a cooperative team from the the approval department, vigilance department and marketing department (GHTF, 2005). Conversely, a study carried out by Siekmeier and Lütz (2007) researching IVD post-marketing surveillance notifications demonstrates that, if a collaboration between these departments is missing, this results, in case of adverse events, in a stop of the distribution of IVD products rather than in collecting and submitting post-marketing surveillance data to health authorities. Another important point influencing post market surveillance is related to the physical attributes of the product, including product information, as surveillance information might also be used as data source to generate leaflets and brochures (Jefferys, 2001). Cornel et al. (2011) claim that standardisation meets the requirements for both the reporting of adverse events such as malfunction of IVD products and the use of post-marketing surveillance data as a starting point for the generation of product information. Furthermore, it is argued that the use of different sources will create misunderstanding and confusion for the customers: the use of a standardised post-marketing surveillance practice might prevent this confusion. This proposition is contradicted by Braga and Panteghini (2014), emphasising that marketing and regulatory affairs managers have to face different international directives and legislation which inhibit the simultaneous use of post-marketing surveillance data for developing safe physical conditions of product, including product information. Hannig and Siekmeier (2014) write that what in this case is needed is the introduction of a directivity matrix in which, according to the national and international rules, adverse events are reported and product information is generated. In

this directivity matrix, the different national and international standards and legislations are handled and updated, thus allowing to report adverse events or to design physical conditions of products which meet respective restrictions (Hannig & Siekmeier, 2014). In this, Hogarth et al. (2010) assert that a well standardised post-marketing surveillance approach helps the company to move from limited interest and an approach characterised by a lack of knowledge to a well-managed approach with advanced, safe, functional and reliable products. By following the recommendation by Hogarth et al. (2010), IVD companies will achieve long-term success by including market surveys, product trials, clinical studies, adverse incidents, user reports, customer complaints, scientific papers in peer-reviewed journals and reports on similar products of competitors as possible sources when systematically gathering information regarding experiences gained on the market. Using these determinants as a paradigmatic basis in terms of post-marketing surveillance standardisation, it is important to review and compare whether these determinants favour or obligate IVD manufacturers to standardise their practices and categorise them accordingly (Bremond & Plebani, 2001 1993; Siekmeier & Wetzel, 2013). This is confirmed by Zhang et al. (2012), emphasising that it is important to analyse whether determinants obligate or favour post-marketing surveillance practices and whether thereby a proper understanding for the development of managerial guidelines of good practice of post-marketing surveillance can be gained. Thereby, "a proper understanding and control […] by strengthening standardisation" is achieved, leading to safer and more effective IVD products (Zhang et al., 2012, p. 519). This is supported by Most (2008), emphasising that this in turn leads to better quality control in manufacturing and the execution of the active vigilance. Most suggests as a starting point five main steps for developing a standardised post-marketing surveillance approach. First, the systematic collection of information with regard to experiences gained on the market in a standardised way, in order to maintain consistency on a global basis.

Second, the analysis of the information gained on the market and its integration within a vigilance system. In this, the use of a standardised post-marketing surveillance approach is of paramount importance, as, according to Donawa (2007), the market vigilance is based on the experiences gained on the market, the first step. The five-step approach proposed by Most (2008) is supported by Sörensen, Landvall, and Lodén (2012), adding that both market vigilance and surveillance are part of the post-marketing surveillance approach, with each step using some information from the other step (see Figure 1). The market surveillance, an 'active process', is the step aiming at understanding experiences with the IVD product through systematically collecting information from different sources, among them vigilance information (Sörensen et al., 2012). Based on this, the market vigilance system analyses the information gained on the market, enabling companies to appropriately communicate with competent authorities (Siekmeier & Lütz, 2007). In this, the directive MEDDEV 2.12/2 clarifies actions to be taken once a manufacturer or a competent authority receives information concerning an incident such as the death of a customer or a serious deterioration in the state of health of a customer due to malfunction or deterioration in the characteristics or performance of the IVD product. The market vigilance system is supposed to be a 'reactive' process, as it involves responding appropriately to experience gained on the market, such as patient reports containing information that an IVD product has caused or may cause harm to customers.

Third, based on the information gained from the incident, manufacturers are expected to take action, for example follow up incident analysis with an investigation of the surrounding circumstances.

Fourth, the dissemination of information is the central focus of this step, whereas the competent authority decides how and in which way the manufacturer has to disseminate the findings. Fifth, change management is introduced to reduce a risk of death or serious deterioration of the customer. In terms of change management, Brolin (2008) writes that a standardised approach is of paramount important to re-direct the use of resources, business process for significantly enhancing safety and effectiveness of products. It is argued that IVD manufacturers, when establishing change management, might define measurable aims and create a business case for their achievement.

A standardised post-marketing surveillance practice not only enables the company to develop and market safe and effective IVD products, but can also be seen as a catalyst for smoothing further administrative hurdles, such as fulfilling requirements for technical documentations. These technical documentations have to be made available for inspection by competent authorities, but can be further used for licensing and CE marketing of IVD products. Santos (2013) went so far as to emphasise that the conceptualisation and simplification of post-marketing surveillance standardisation enables the company to market IVD products more effectively, thus generating economies of scale.

Figure 1: Post-marketing surveillance strategy
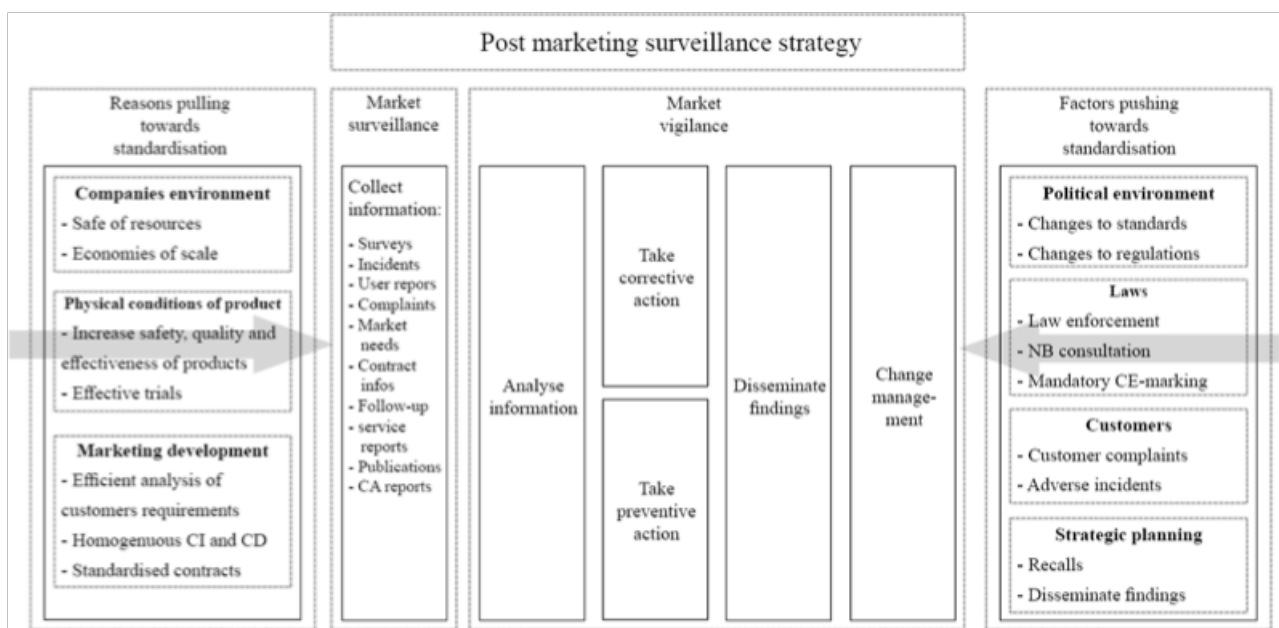
In addition, Kawahara (2009) argues that standardising the post-marketing surveillance practices is vital and essential for meeting both customers' wants and regulatory requirements. It is expected that competent authorities will further enforce the implementation of standardised post-marketing surveillance practices (Most, 2008), thus better protecting the health and safety of patients by enhancing the standardisation of these practices (Lim, 2010). In fact, IVD products are often life-saving which means that any malfunction of such a device can result in the deterioration of a patient's health, whereas the post-marketing surveillance practices only can be effective if they are highly standardised (McNerney et al., 2014). Not only the enforcement of implementing standardised practices is important, but the consistent collection and evaluation of post-marketing data and the reliable dissemination of information, as appropriate, help companies to meet customers' real needs, reinforce their image and alleviate consequences in the case of an incident (IVD, 2011). For IVD manufacturers to be successful they have to incorporate the factors pertaining to post-marketing surveillance in

a standardised way. Thus, achieving the safety and effectiveness of IVD products means more than simply fulfilling regulatory responsibilities, whereas these companies must try, on the one hand, to collect and evaluate marketing data regularly, but also, on the other hand, to introduce a market vigilance system and conduct field safety corrective actions where necessary, including withdrawals and recalls, in order to satisfy regulatory needs. Not only may failure in post-marketing surveillance result in noncompliance and liability issues (Braga & Panteghini, 2014), but the goal of reducing costs and regulatory/ marketing complexity also leads IVD manufacturers to implement a standardised approach (Gupta, 2016). In this, Lim (2010, p. 217) argues that it is worth noting that post-marketing management "may well be the most resource-intensive phase for manufacturers" placing IVD products on the market. It is further emphasised that post-marketing surveillance depends upon several determinants grouped into 'reasons' and 'factors' (Vrontis, 2003). Based on the study by Vrontis (2003), the author Most (2008) further argues that there is an inherent need to study the significance of each of these determinants impacting post-marketing surveillance standardisation. In this context, determinants are separated, on the one hand, into reasons, defining behavioural aspects, pulling or in other words favouring IVD manufacturers towards a standardised approach (e.g. the development of products according to customers' needs and cost-reduction because of streamlining the regulatory process for in vitro diagnostic devices), and, on the other hand, into factors which are the determinants pushing, in other words obligating, manufacturers towards a standardised approach (e.g. obligations to meet regulatory requirements and the enforcement of mandatory reporting of incidents), affecting companies' behaviour and its relative importance.

Determinants of post-marketing surveillance standardisation

The isolated management of determinants impacting a standardised post-marketing surveillance approach is rejected by various authors, highlighting difficulties to apply isolated determinants in practice (Henningfield & Schuster, 2009; Most, 2008; Pirmohamed & Lewis, 2004). In this, Lim (2010) states that particular determinants might, at the same time, both favour and obligate IVD manufacturers in terms of their post-marketing surveillance standardisation. When manufacturing IVD products, an enterprise has to go far beyond simply interchanging information with notified bodies and becomes much more directly involved in collecting, analysing, scrutinising and sharing information within a given market or country. Marketing and regulatory affairs managers are likely to have their own sales subsidiaries and, based on this, to participate in developing new post-marketing surveillance tactics. Therefore, Most (2008) recommends the centralisation of decision-making and thereby managing determinants influencing this approach in a centralised way. This is particularly true for laws within a certain market, handled as a pushing determinant in terms of post-marketing surveillance standardisation, obligating IVD manufacturers to standardise their procedures, particularly regarding NB consultation and mandatory CE marking. At this point, further determinants are categorised by Lim (2010), emphasising that political environment (changes to standards, changes to regulations) and customers (customers' complaints, adverse indecent management) are two main factors pushing IVD manufacturers towards standardisation. Kawahara (2009) argues that grouping these factors helps enterprises to standardise post-marketing surveillance according to the market conditions. Heterogeneity among different countries, particularly true for the European Union (Kanso, Nelson, & Kitchen, 2015; Quelch & Hoff, 1993; Reid, 2015), obligates IVD manufacturers to fully standardise their post-marketing surveillance approach. Sörensen et al. (2012) concentrate on a further factor to examine IVD manufacturers' post-marketing surveillance behaviour, namely strategic planning. They

note that strategic planning includes recalls and the dissemination of findings (Sörensen et al., 2012). Furthermore, they argue that a post-marketing surveillance activity will be a very successful activity when reasons pulling towards standardisation are communicated by notified bodies and competent authorities. For IVD manufacturers, reasons pulling towards standardisation enable them to be successful, because the main reason company's environment (decrease consumption of resources, safes due to economies of scale) leads automatically towards the incorporation of a standardised post-marketing concept (Most, 2008). Thus, effectiveness and reaping the benefits of post-marketing surveillance standardisation mean that these companies also improve the physical condition of their products, increasing the safety, quality and effectiveness of these products and making trials more effective. This is further underlined by Campbell (2007), arguing that a decision on standardisation also enhances marketing development, pulling IVD manufacturers to efficiently analyse customers' requirements and enabling them to standardise customers' contracts. The successful incorporation of post-marketing surveillance will therefore lead to a greater consideration of the pulling reasons and pushing factors affecting standardisation behaviour and its relative importance. Both determinants are shown in Figure 1 and it is further noted that grouping the determinants is particularly appropriate when researching post-marketing surveillance (McNerney et al., 2014; Most, 2008).

Research scope and methodology

Scope of the research

The debate about a standardised post-marketing surveillance approach for IVD manufacturers has become more and more prominent and is, as discussed, of great importance. There is a strong need for IVD manufactures not only to standardise their post-marketing surveillance practices by collecting experience gained on the market and market vigilance for communicating incidents, but also to implement them into the overall-business approach. It is evidenced that this practice is not a dichotomous decision, as both market vigilance and post-marketing surveillance use information from the other step. Because of this, they can be seen as a single entity. This research investigates the factors impacting safety-oriented post-marketing surveillance practices and evaluates the relative degree of significance of each of the reasons pulling IVD manufacturers towards a standardised approach and of the factors pushing the company towards this direction. In this, the research investigates the strategies and tools adopted by European IVD manufacturers. The objectives of this research are to:

- develop a variable based on European IVD companies' post-marketing surveillance behaviour, and to place IVD companies on a linear continuum, indicating whether the determinants observed push or pull to post-marketing surveillance standardisation;
- examine the extent to which the various reasons and factors influencing European IVD manufacturers' post-marketing surveillance behaviour towards the standardisation of this practice, through the application of a statistical modelling; and
- critically discuss the results and present the managerial implications of the observed overall behaviour of European IVD manufactures regarding the standardisation of post-marketing surveillance practices.

Research methodology

This research is based on 246 IVD manufacturers based in Europe, whereas more than 68% of these IVD products are directly sold in Europe (EucoMed, 2016). This paper

focuses particularly on the European IVD branch, being one of the biggest in the whole world and Europe being the leading IVD nation (EucoMed, 2016). The fact that this research focuses on European-based IVD manufacturers is only a methodological limitation and, therefore, limits the direct generalisation of the findings. For this research, questionnaires were prepared and mailed to the marketing and regulatory directors of these IVD manufacturers. In terms of the response rate, 92 questionnaires where completed and returned, being utilised as the basis for this research. In this, the research is non-probabilistic, focusing on judgment sampling, whereby cases are selected according to their characteristics or contextual location (Perla & Provost, 2012). The sample was split between business-to-business with 36.25% and business-to-consumer with 63.75%. For the questionnaires, both open and close-ended questions have been used, whereas behavioural variables were added to this study. These variables were introduced to investigate IVD manufacturers' behaviour towards post-marketing surveillance practices and the determinants relating to this behaviour. In this, behavioural variables are very helpful in critically investigating companies' practices and their factors influencing these practical circumstances (Schwede, 2007). In this research, the behavioural variables elicit whether IVD manufacturers are pushed or pulled towards a standardised post-marketing surveillance approach by the determinants explained in the literature review, influencing this practice. Furthermore, several attribute variables have been established, containing the interviewees' characteristics and helping to analyse something which a respondent possesses rather than something which a respondent does (Vignali, Gomez, Vignali, & Vranesevic, 2001). These attribute variables helped in examining the various determinants influencing companies' behaviour towards a safety-oriented post-marketing surveillance practice and the identification of different sub-determinants to be standardised. For this research, the rating scale 'Rasch model' and structural equation modelling have been used in order to address the research objectives. Based on a description of the 'Rasch model' and the structural equation modelling used for this study, the technical details of the statistical analysis are explained in order to enable repeatability and replicability. The principle of replicability is widely acknowledged to be fundamental to scientific progress, particularly in terms of statistical analysis, allowing the generalisation of findings and confirmation of results (Hubbard, Brodie, & Armstrong, 1992). The Rasch model was first proposed in the early 60s for the evaluating of ability tests, particularly for the evaluation of behaviours and attitudes in terms of a questionnaire developed (Battisti, Nicolini, & Salini, 2010). When looking to analyse attitudes in terms of organisational practices, the Rasch model seems to be particularly appropriate. Several sources report that, particularly in quantitative sociology and marketing studies, the use of the Rasch model seems to be appropriate (Böckenholt, Barlas, & Van Der Heijden, 2009; Salzberger & Koller, 2013; Vignali et al., 2001). In the area of post-marketing surveillance research, Hubbard et al. (1992) used the Rasch modelling for the critical examination of data from post-marketing studies of drugs, developing a model to enhance the quality of companies' marketing activities, thus enhancing the drugs' quality and efficacy. Another study, carried out by Montague (2010), researches the validation of post-marketing surveillance data in the medical device industry. The researcher encouraged other scientists to use the Rasch model, emphasising that this statistical method plays a prominent role in monitoring the safety profile of marketed medical devices, particularly in terms of post-marketing surveillance practices. According to Paliwoda, Slater, Vrontis, Thrassou, and Lamprianou (2009), this method gained considerable relevance, particularly in the marketing research domain, as it guides a researcher by quantitatively measuring managers' reactions to a proposed marketing strategy. This is underlined by Ewing, Salzberger, and Sinkovics (2005, p. 17), stating that the Rasch model is particularly helpful to "test standardized […] environments". Furthermore, the Rasch model is particularly

helpful in validating a proposed construct (Commons et al., 2008) and therefore perfectly suits the needs of this research, as the Rasch model is used to reconstruct the IVD manufacturers' tendency in terms of whether their post-marketing surveillance practices are pushed or pulled by the determinants identified. In this, the judgement of whether the Rasch model is valid for this study or not is based on model-data fit criteria. These criteria provide further statistical evidence of determinants pushing and pulling IVD manufacturers towards standardised post-marketing surveillance. Several studies evidenced that the Rasch model, in comparison to other statistical approaches used in marketing research (e.g. reliability analysis, factor analysis, marginal maximum likelihood estimation), has a higher precision and accuracy and provides a stronger justification of the equivalent of the measure related to individual respondents (Saleem & Larimo, 2017; Sinkovics, Salzberger, Salzberger, & Sinkovics, 2006). This is confirmed by Alvarez and Galera (2001), outlining that the Rasch model is particularly appropriate when the research focuses on the relations between factors impacting a proposed marketing approach. Other researchers such as Parra-López and Oreja-Rodríguez (2013) and Ismail et al. (2016) recommend future uses of the Rasch model in marketing surveillance studies, emphasising that specifically in terms of meaningfulness and justification it plays a crucial role, as it acknowledges non-linearity and transforms raw data into a linear and interval-scaled measure by the use of a logistic function. This is further evidenced by London (2016), stating that the equal interval measures transformed by the Rasch model are used to map marketers' practices onto a linear (interval) scale. Doğan (2012, p. 6) states that the ordinal measurement scale should be converted into interval measurement, thus "providing a more appropriate data for analysis". In this, the Rasch model fits in perfectly, as the measurement model converts the ordinal measurement into interval measurement by benefit from logit distances (Doğan, 2012). In this, the Rasch model allows for the conversion of the ordinal scale into the interval scale, as it is applied by several Likert questions in this research. The Rasch model is the model of choice to transform Likert questions for the production of one single overall index in terms of the underlying post-marketing surveillance behaviour towards standardisation. For this research, the Rasch model tests whether a single latent trait actually underlies a number of Likert questions used in this study. It is important to mention that for this study it is assumed to be unidimensional, as it represents a fundamental methodological assumption to conceptualise several Likert questions to measure the same latent variable. The underlying latent variable is used to measure European IVD manufacturers' post-marketing surveillance behaviour towards standardisation, impacted by various reasons and factors. In short, this research will not elaborate theoretical properties or further assumptions of this model (Paliwoda et al., 2009). For every IVD manufacturer participating in this research, a single standardisation measure was estimated by the Rasch model, using companies' responses to each of the Likert questions. In this, a bigger value indicated that a certain determinant has a certain tendency to push towards the standardisation of post-marketing surveillance activity, whereas a smaller or negative value indicates pulling towards its standardisation. Several studies researching companies marketing practices use the Rasch Rating Scale Model also used in this research (Bechtel, 1985; Laurent, Kapferer, & Roussel, 1995; Paliwoda et al., 2009; Sinkovics et al., 2006).

$$\ln \frac{P_{nik}}{P_{ni\,k-1}} = \theta_n - B_{ik}$$

According to Vinzi, Trinchera, and Amato (2010), the Rasch rating scale model is particularly helpful when examining responses from seven-point Likert scales on behavioural and attitudinal data, where a respondent n answers a certain question, rated on a Likert scale of k categories. In this, θ_n represents the companies' ability or attitude

measure; Bik indicates the difficulty measure of an item, which is, in terms of this research, the difficulty of the question. It is further worth mentioning that for this research, the Rasch rating scale modelling provides a score between 1 to 7 on every question posed to the subject and is handled as a score category. Therefore, all Likert questions employ the same rating scale and maintain at all times the same meaning across the study. The equation illustrated above shows the case where all these Likert questions maintain the same rating scale. Nevertheless, the use of raw scores is not compatible with this study, as some questions are not applicable to all IVD manufacturers. As an example, the question about effective and efficient trials might be mentioned, as not all IVD manufacturers do employ trials. The 'question free' nature, thus overcoming the challenge of missing responses, is one of the major advantages of the Rasch rating scale modelling (Willmott, 1978). Several marketing research papers indicate that this is one of the desirable psychometric properties of the Rasch rating scale modelling, as the estimation of the attitude measure for each of the marketing practitioners is "question free", that is, any failure to answer "all questions in the questionnaire does not affect the comparability of the estimated attitude measures" (Charalambous et al., 2005, p. 1307). The infit and outfit MNSQR statistics were also computed in order to investigate the fit of the data-model fit. Both infit and outfit MNSQR for the IVD manufacturers and questions have been evaluated very carefully, and, based on the residual matrix, the response patterns have been investigated. The MNSQR draws extensively on the guideline developed by Linacre (1999, 2006) in order to construct infit and outfit statistics on a unidimensional scale. Each of the Likert questions employed in this research has been designed under the header "Does the following determinant enforce or facilitate the standardisation of your company's post-marketing surveillance activity?". Both terms, enforcement and facilitation of standardisation, are further explained in the questionnaire in order to ensure an appropriate understanding of and response to each of the categories. In this, the Likert scale ranged from 1-7, where 1 represents 'fully pushed', 4 represents 'neutral' and 7 means 'fully pulled'. The answers of the interviewees provide insights whether a determinant pushes or pulls the standardisation of IVD manufacturers' post-marketing surveillance practices. Each of these Likert questions is employed to get a single measure in terms of the tendency of respondents' attitude to be pushed or pulled towards the standardisation of their post-marketing surveillance practice. More specifically, the respondents' answers were used to estimate as reliably as possible a single overall standardisation attitude for each IVD manufacturer. Therefore, the first objective of this research is fulfilled. Each of the responses on the Likert scale is used to determine the location of the IVD manufacturers' standardisation behaviour, whether pulled or pushed, and to place it on a linear continuum. For addressing the second objective of this research, this variable then was used to further identify the extent to which each of the various determinants may lead towards the standardisation of this practice. For answering this research objective, statistical equation modelling was used. In this, the answers to the questions "When developing, manufacturing and distributing an IVD product, which determinants facilitate the standardisation of your post-marketing surveillance practice? To what extent do these determinants facilitate your post-marketing surveillance practice?" and "When developing, manufacturing and distributing an IVD product, what determinants enforce you how much to standardise your post-marketing surveillance practice?" are used as predictors in a regression modelling of the location of IVD manufacturers on the Rasch scale. Nevertheless, the use of multiple regression in this study is realised through the simultaneous use of several equations and regression models. This is supported by Heinz (2009), emphasising that for marketing research the simultaneous use of various regression models allows model mediation and the observation of indirect relationships as well as of effects between the determinants occurring. Besides observing simultaneous

effects of several dichotomous variables, the development of a comprehensive theoretical model is facilitated. This is particularly true for the questions with regard to which of the various determinants influence European IVD manufacturers' post-marketing surveillance practices. The answers regarding the extent to which the various reasons and factors influence post-marketing surveillance practices might be affected by an underlying construct and are, therefore, hypothesised in this research. This is particularly true with respect to the regulatory constraints of each IVD manufacturer, pushing or pulling towards standardisation. This is the reason why the structured equation modelling is formative, as this research assumes that the answers do not reflect the idiosyncrasy of each IVD manufacturer. This hypothesis is tested by using the answers to the question which of the various reasons and factors influence post-marketing surveillance practices. The responses to these questions are used as variables and applied within a measurement model where intercorrelations between these variables are allowed. Furthermore, it is difficult to 'practically prove' whether the choice of a formative model (not reflective) is right or not, as the choice towards a formative model is based on theoretical reasons (Paliwoda et al., 2009). Several researchers mention that a formative model has the advantage of not altering the content of the structured equation model (Casagranda, Colazzo, Molinari, & Tomasini, 2010; Vinzi et al., 2010). Furthermore, the sample size of this research allows the estimation of structured equation modelling parameters which are not biased. Model fit information is one of the most convincing empirical evidence to support a structured equation modelling, and the sample size of this research allows accurate model fit information (DiStefano & Hess, 2005). In accordance with Paliwoda et al. (2009) and Lei and Wu (2007), the evaluation of the model is carried out with statistically insignificant $\chi 2$ criterion, a root mean square error of approximation of less than 0.6, conformity fit index higher than 0.95 and Tucker-Lewis Index higher than 0.9. For calculating the Rasch rating scale model Xcalibre 4.1 and for the structured equation modelling SPSS Amos Version 22.0 have been used.

Results

The results show that the Rasch rating scale modelling allows for a successful operational definition in terms of measuring IVD manufacturers' attitude towards post-marketing surveillance standardisation. Therefore, the Rasch rating scale modelling has been an appropriate selection with regard to the data set of this study. It is further demonstrated that there is an acceptable model-data fit, particularly true in terms of questions, rating categories and IVD manufacturers selected for this research. In terms of the Likert scale, ranging from 1 to 7, none of the categories has a higher outfit MNSQR than 2.0, being thereby conform according to Linacre (1999) suggestion. Furthermore, there have been many observations for each category, and the average measure of IVD manufacturers relating to each category is increasing. Nearly none of the questions has shown unusual statistics, but categories in the facets of questions with unusually high fit statistics (any value above 1.2) have been investigated in more depth in order to identify the source of the deviation. This is the reason why model-data fit can be assumed to be sufficient with respect to the standardisation variable decisiveness and therefore, this research further proceeds with the analysis of the standardisation variable determined for this study. The Rasch rating scale modelling on the Likert questions shows that European IVD companies' post-marketing surveillance behaviour is reflected by a vertical continuum. In this, the similarity of the behaviour index to the Rasch scale is within a marginally acceptable separation reliability coefficient of 0.58. For the interpretation of this linear continuum (see Appendix 2) it is important to consider that a determinant at the bottom of the scale demonstrates a strong tendency towards pushing IVD manufacturers towards

standardisation and therefore favouring the standardisation of post-marketing surveillance practices (e.g. the development of products according to customers' needs and cost-reduction because of streamlining the regulatory process for in vitro diagnostic devices). Determinants represented at the top of the Rasch scale demonstrate a very strong obligation for the IVD manufacturers towards standardisation. In this, it is important to consider that the determinants at the bottom of the Rasch scale are easier to answer in terms of favouring standardisation, as they pull towards a standardised approach, thereby enabling IVD manufacturers to reduce costs, fulfill market needs and develop products more efficiently. The determinants pushing towards standardisation are shown at the top of the scale and represent factors which represent an obligation for IVD manufacturers to standardise their approach. It is very remarkable that IVD manufacturers' post-marketing surveillance behaviour and attitudes in terms of the same category (initially categorised by the researcher of the questionnaire) fit very well together and form clusters, within which the IVD manufacturers tend to show the same behaviour towards determinants representing an obligation or favour towards standardisation. In terms of factors favouring standardisation the hierarchy is very clear, as minimisation of resource consumption represents the cluster of questions where IVD manufacturers indicated a clear tendency of favouring, that is pulling standardisation. On the other side of the continuum obligatory NB consultation clearly indicates a determinant pushing towards the standardisation of post-marketing surveillance practices, representing an obligation to standardise this activity. The Rasch rating scale confirms the initial clustering of the different determinants within the questionnaire, pulling and pushing towards standardisation. In this, the IVD manufacturers seem to standardise their post-marketing surveillance practices in distinct ways for different determinants of the post-marketing surveillance approach. The Rasch rating scale clearly confirms that the Likert questions provide a reliable and valid basis for the design of a unidimensional questionnaire. Therefore, this unidimensional questionnaire can be used to measure tendencies towards the IVD manufacturers' standardisation of their post-marketing surveillance practices. Furthermore, the Rasch rating scale perfectly satisfies the need for a valid tool in terms of this research, fulfilling the first research objective satisfactorily. In this, the structured equation modelling was used to represent the extent to which the various reasons and factors influence European IVD manufacturers' post-marketing surveillance behaviour towards its standardisation, represented by the standardisation variable within the Rasch scale. The standardisation variable was constructed by the IVD manufacturers' answers with respect to the Likert scales regarding their standardisation behaviour. The model-data fit has been investigated extensively through numerical methods, evidencing that the results are robust and that the data fit is satisfactory for all purposes and intents of this research. In this, CFI was 0.983, and RMSEA was 0.0386, suggesting adequate model fit. The χ 2 test of model data fit was not significant (χ 2 = 29.946, df = 17, p = 0.063). In terms of the Tucker-Lewis Index (TLI), it should be 0.95 and higher and close to 1.00, and with a value of 0.962 a fitted model in this research is provided. Furthermore, an inspection of the modification and the residual values revealed no significant points of misfit in the model. It is observed that there is a number of determinants significantly favouring and thereby pulling towards standardisation. Particularly, the factor company's environment in terms of minimisation of resource consumption/increase of economies of scale and the factor physical conditions in terms of increased product safety and effectiveness are among the reasons very strongly pulling towards standardisation. In other words, for IVD manufacturers these factors have a significant and practical impact on the construct underlying standardisation. On the other hand, it has to be mentioned that these three factors are the only statistically significant factors contributing to the model.

Figure 2: Full structural model with standardised coefficients
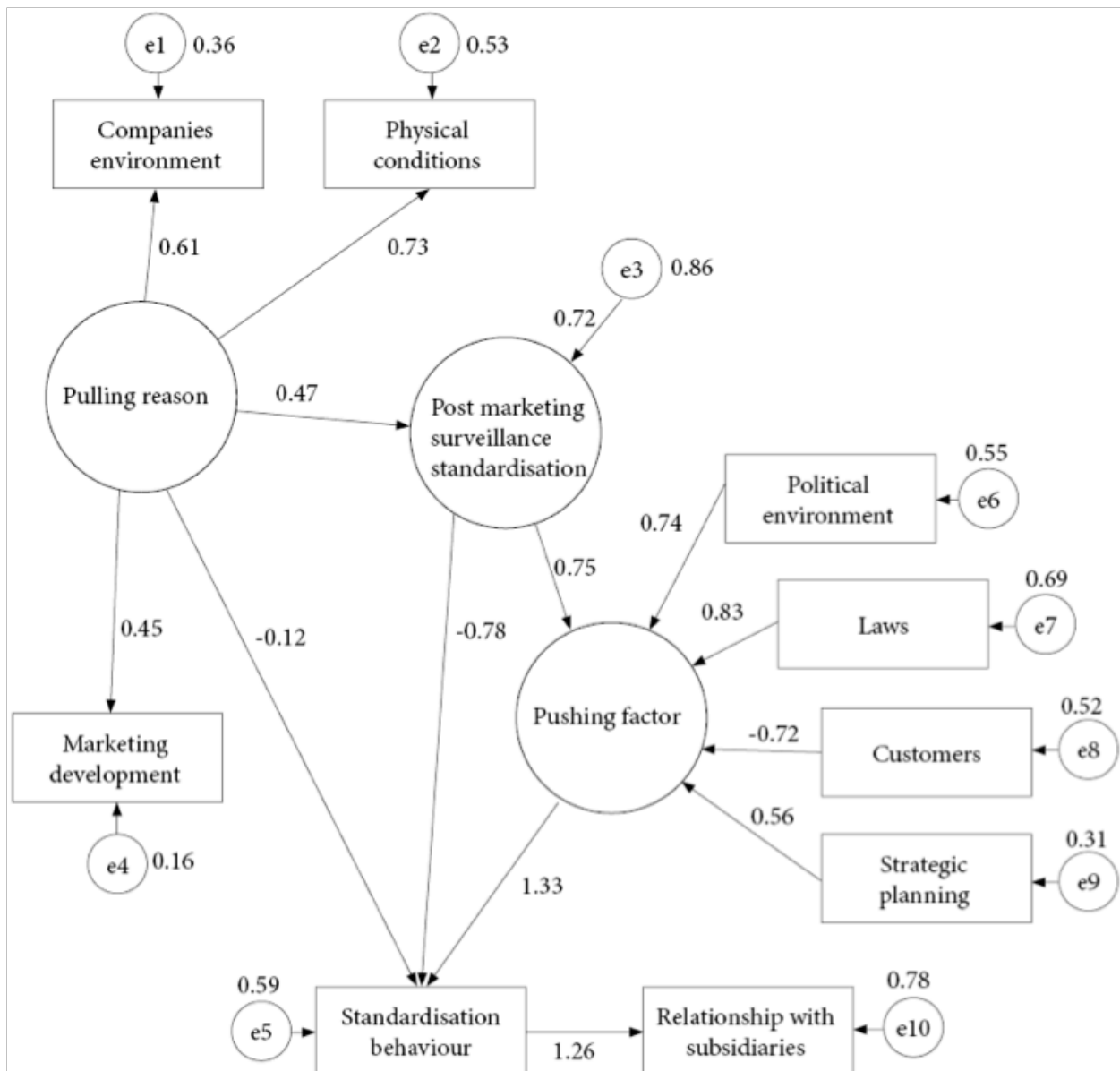
The two determinants established for this research – pulling reasons and pushing factors – contribute to a single overall attitude for each IVD manufacturer. These two determinants in turn affect the standardisation behaviour of the head quarter (e.g. the answers of each IVD manufacturer in terms of the Likert questions posed to the marketing and regulatory affairs managers by the questionnaire) and subsidiaries of an IVD manufacturer. It is important to mention that the magnitude of the statistical weight of factors obligating enterprises to standardise their post-marketing surveillance approach is almost twice that of the favouring factors in terms of the standardisation construct. In other words, it can be inferred that the obligation to standardise post-marketing surveillance practices is more powerful than the need to standardise this approach, which is reflected by the pulling reasons. Four determinants have been identified as pushing towards the standardisation construct, whereas there are only three determinants pulling towards this standardisation construct. Several alternative statistical equation models have been tested in terms of this theory. The variables included within this model, as depicted in Figure 2, provide high data model fit and in turn retain a valid theoretical basis. This also reflected by the high

evidence of unidimensionality, thereby leading to optimal model fit statistics. The significant level of factor loading is based on the value of critical ratio, whereas a minimum critical ratio value of 1.960 is required for the factor loading to be significant (Byrne, 2013). It is further shown that all weights in terms of regression are statistically highly significant by a critical ratio of more than 2.689. The largest standardised weight in terms of factors pushing post-marketing standardisation belong to political environment and laws. Strategic planning is the pushing factor with the lowest standardised height.

Conclusions and managerial implications

There has been a long discussion with regard to the question which determinants in post-marketing surveillance obligate IVD manufacturers to standardise their approach. In this, there has been a long debate whether the fortification of reasons favouring this approach might help enterprises to standardise their approach, promulgating clearly favouring reasons such as minimisation of resource consumption and economies of scale. This discussion continues to be a research focus of high relevance in academic literature, whereas it is also of ongoing and significant concern for every regulatory and marketing manager. This research found it to be an irrational practice to obligate IVD manufacturers to establish principal mechanisms for managing the surveillance and vigilance of their post-marketing practices, as there seems to exist a principal need in standardising these activities, such as minimisation of resource consumption, the enhancement of the products' safety, quality and effectiveness. It is also true that this principal need automatically drives IVD manufacturers towards a systematic and standardised collection, analysis and sharing of information regarding their products. Furthermore, it appears to be irrational for IVD manufacturers to attempt to the complete standardisation of their post-marketing surveillance practices without a clearly defined set of determinants and precisely identified categories, being managed in a well-organised post-marketing approach. In fact, for IVD companies it is difficult to offer and market their products without standardised strategies, because this may result in exorbitant marketing costs and decreased product safety and effectiveness.

In marketing IVD products, an enterprise has to make fundamental decisions about surveillance and vigilance mechanisms, affecting customers, business and society everywhere. This is, therefore, an issue which cannot be buried within bureaucratic burdens and seen as an encumbrance to be addressed for fulfilling mandatory regulatory requirements. A crucial question, therefore, is: What should IVD manufacturers do when facing decisions in terms of post-marketing surveillance standardisation? Recent research clearly evidences that on a tactical level (determinants influencing post-marketing surveillance) it is wisely to introduce a systematic approach which is likely to drive and enhance business (Hogarth et al., 2010; Siekmeier & Lütz, 2007; Zhang et al., 2012). In line with statistical and empirical research this research is carried out and further developed based on Most (2008) five step approach to post-marketing surveillance standardisation. This approach, further developed by Sörensen et al. (2012), is influenced by determinants which are, on the one hand, pushing companies' attitude and, on the other hand, pulling them towards this approach. There exists a clear need to standardise post-marketing surveillance on a business level and adapt the determinants (e.g. physical condition, political environment) according to the country or region where the product is marketed. The standardisation of this activity does not mean the operation of marketing strategy and tactics in a 'glocalised' way (thinking globally and acting locally). Rather, this means standardisation where possible, whereas 'unwarranted generalisations' from one post-marketing surveillance situation to another have to be avoided at any time and at all

costs, as every market, IVD product and customer can be very distinct. Regulatory affairs and marketing managers therefore should understand that there is a thin line between the advantages arising from using a standardised approach and the risk of seeking a level of marketing homogenisation. Furthermore, when deciding to employ a post-marketing surveillance approach it does not seem to be a one-off choice to be taken only once in business development. Much more, IVD manufacturers are required to aim to achieve a well-adjusted balance between the determinants pushing and pulling standardisation and to decide thereof how to standardise. Marketing IVD products all over the world means for the enterprise to simultaneously focus its resources and strategic planning on those issues of the post-marketing surveillance approach that require a high level of standardisation and upon factors such as customers that require local market awareness. Therefore, the enterprise has to focus on introducing a standardised post-marketing surveillance approach, driven by the pulling reasons. However, customers and the political environment in different markets also require a certain flexibility. This is the reason why IVD manufacturers have to strive for a standardised approach, highly standardising pulling reasons and standardising pushing factors towards a well-balanced regulatory and political practice. Standardising pulling reasons seems to be a very straightforward task, particularly when faced with similar physical product conditions and company's environment, whereas the standardisation of pushing factors seems to demand much more local responsiveness, particularly when facing different political environments with different laws. Thus, the standardisation of pushing factors is a difficult task and has to be developed in an ongoing way. Nevertheless, this research has demonstrated that post-marketing surveillance standardisation is not a one-off and one-time decision, whereas pulling reasons on the one side of the continuum seem to be standardisable in a straightforward manner and pushing factors seem to be a matter of degree. In standardising pushing factors, the matter of degree also depends very much on marketers' experience and the IVD manufacturers' market and standardisation knowledge. It is demonstrated that minimisation of resource consumption and economies of scale are the main drivers for IVD manufacturers, pulling post-marketing surveillance standardisation in a tremendous way. On the other hand, the risk of huge resource and time consumption when not standardising this approach, together with the desire to reap its advantages, makes the standardisation of pushing factors for IVD manufacturers even more attractive. For standardising both surveillance and vigilance activity, the organisational differences, particularly between subsidiaries, have to be kept at a minimum level. A centralised business strategy and structure, therefore, seem to be preferable, thus allowing post-marketing surveillance standardisation to be practiced extensively. From a managerial point of view, IVD manufacturers therefore should incorporate a centralised approach based on clear decision-making combined with a strong regulatory and marketing understanding of the market where the company's products are offered and sold. The results clearly evidence that the post-marketing surveillance reasons pulling towards standardisation do not, in comparison to the factors pushing towards standardisation, bear the same level of significance for IVD manufacturers' standardisation behaviour. It was found that they can be separated into "peripheral" and "significant" ones, both of them affecting the post-marketing surveillance strategy, although the former do so to a lesser extent. In this, Figure 3 illustrates these reasons pulling and factors pushing towards post-marketing surveillance standardisation, incorporating the results of this study. The results show that "physical conditions of product" and "company's environment" are significant reasons pulling towards standardisation and these determinants were termed as such. In this, "marketing development" was found to have a smaller significance as a reason pulling towards standardisation. This is the reason why this factor was termed peripheral reason pulling towards standardisation. In comparison, "political environment" and "laws" are

significant factors pushing towards standardisation, in other words, obligating manufacturers to do so. It was found out that the determinant "customers" is seen by IVD manufacturers as a significant reason pulling towards standardisation and not, as defined in the literature, as a factor pushing towards standardisation (Most, 2008; Siekmeier & Lütz, 2007). In this, "strategic planning" is the only factor considered to have with less significance and is accordingly categorised as peripheral factor pushing towards standardisation. The specific results carry a significant value in terms of understanding IVD manufacturers' behaviour concerning post-marketing surveillance standardisation. This study empirically provided an insight into the determinants underlying related decisions and, what's more, weighted their relative importance with respect to post-marketing surveillance standardisation. Besides the empirical value and academic contribution to knowledge, this research enables managers to understand IVD manufacturers' approaches in terms of adjusting their post-marketing surveillance behaviour regarding standardisation accordingly. The results of this study clearly outline that no IVD manufacturer does or should ever make only a one-time and one-off decision when post-marketing surveillance standardisation is concerned.

Table 1: Regression weights of structured equation modelling

Regression weights:	Estimate	Standard Error	Critical Ratio	P
Pushing factor ← Post-marketing surveillance standardisation	2.892	0.645	4,483	*
Post-marketing surveillance standardisation ← Pulling reason	1.613	0.524	3,078	0.004
Pushing factor ← Political environment	1.000			
Pushing factor ← Laws	-0.762	0.598	-1,274	0.010
Pushing factor ← Customers	1.494	0.137	10,905	*
Pushing factor ← Strategic planning	1.624	0.128	12,687	*
Company's environment ← Pulling reason	0.400	0.097	4,123	*
Physical condition ← Pulling reason	1.686	0.206	8,184	*
Marketing development ← Pulling reason	1.496	0.261	5,731	*
Relationship with subsidiaries ← Standardisation behaviour	1.000			-
Standardisation behaviour ← Post-marketing surveillance standardisation	-0.247	0.064	-3,859	*
Standardisation behaviour ← Pulling reasons	-0.619	0.055	-11,254	*
Standardisation behaviour ← Pushing factors	1.506	0.268	5,619	*
Note: *Significant at 0.001				

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Figure 3: Significant and peripheral determinants towards standardisation (research-produced)

This tasks seems very much to be an issue, particularly from the perspective of notified bodies, to be communicated as a process where enterprises can gain considerable benefits in terms of a decrease in resource consumption, cost saving and increase in profit. In this, any competent authority should refrain from communicating it as a law enforcing act and obligation to be fulfilled by every IVD manufacturer, as the underlying results and true values, such as the increase of safety, quality and effectiveness, are a necessity and not an obligation (McNerney et al., 2014). IVD manufacturers should implement both surveillance and vigilance activities into one standardised approach to be integrated within the overarching business strategy. In this, regulatory affairs and marketing managers have to provide sufficient knowledge in order to carefully and efficiently manage this approach. Executives furthermore must focus their attention on the determinants influencing post-marketing surveillance, particularly the determinants political environment and laws, as these determinants require cautious global standardisation and represent aspects that require a high level of local responsiveness. The driving forces behind post-marketing surveillance standardisation are the provision of safe products, the fulfilment of customers' needs and a thoughtful/vigilant customer complaint management. IVD management attention must continually be directed towards the underlying dynamics of the markets which they serve.

The significant amount of studies in the field of post-marketing surveillance which has already contributed to knowledge in the field of medical device manufacturers does not lessen the need for even more. This is particularly true for IVD manufacturers, as there is a huge need to get a "proper understanding and control [...] by strengthening standardisation" in post-marketing surveillance (Zhang et al., 2012, p. 519). This refers both to the study of IVD manufacturers' post-marketing surveillance behaviour and to the multi-aspect integration of determinants influencing standardisation in this field. This empirical research significantly contributed to knowledge in four ways. First, this study corroborated the findings of past research, placing IVD companies on a linear continuum; examining their overall behaviour towards post-marketing surveillance standardisation; developing a standardisation variable based on companies' standardisation behaviour and

attitudes; and empirically examining the relationship between pushing and pulling determinants and post-marketing surveillance standardisation. Second, this study has been realised through advanced statistical analysis, contributing value through scientifically reliable conclusions. Third, this research categorised the reasons pulling and factors pushing towards post-marketing surveillance standardisation into 'significant' and 'peripheral'. Fourth, this research provided highly valuable insights into the practical application of standardisation, with regard to both of surveillance and vigilance of post-marketing activities. It is true that this research only took one scientifically confident step towards a better and reliable scientific understanding in a complex field of study with lots of determinants interrelating within a highly complex approach, entangled, on the one hand, in the prescriptive direction and, on the other hand, in the descriptive comprehension of post-marketing surveillance. Particularly in recent years, the discussion, both from an academic and a practitioner's point of view, has gained in importance and the scholarly debate seems to become wiser and more experienced in its nature. This is the reason why research not only has to incorporate quantifiable and reproducible data, but also might harvest fruitful qualitative insights and experiences provided by academics and practitioners. This research serves as a first scientific step to that.

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Influence of knowledge and innovation potential on the efficiency of clusters – results of empirical research

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Abstract

The organization, to be fully competitive in the global and local market should have and absorb the knowledge and know how to use their knowledge. Knowledge management is particularly important in the case of network organizations that build their capacity through the appropriate use of resources, tangible and intangible assets, and improve the process of interactive learning. A key task for network managers is to stimulate the flow of knowledge between the different actors. Improving the flow conducive to the spread of knowledge, and stimulate the desire to share knowledge affects the level of innovation.

The research in the article is the potential of knowledge and innovation, which must be understood as all the factors affecting their ability to effectively implement projects of innovative character. It is a set of interrelated elements of resources, which, thanks to their work will be transformed into a new state of affairs - with capabilities specific measures and force the creation of new values. The effectiveness of such actions is one of the most important determinants shaping competitiveness of the network.

This article aims to assess the impact of the potential of knowledge and innovation clusters efficiency. Used for this purpose the results of research conducted in 2013, which was conducted in 63 clusters operating in various industries in Polish.

To evaluate the effectiveness of the surveyed clusters will be used multi-criteria evaluation of aggregate taking into account the established standards and evaluation criteria. In order to examine the effect of the potential of knowledge and innovation efficiency of the surveyed clusters will be used linear model.

Keywords: clusters, innovation, efficiency, knowledge, network

Preliminary remarks

In order to be fully competitive on the global and local market, an organisation should possess and absorb the knowledge and be able to use it. Knowledge management is particularly important in the case of network organisations that build their potential through the appropriate use of tangible and intangible assets and improve the process of interactive learning. Stimulating the flow of knowledge between different entities is an essential task for network managers. Improvement of the flow is conducive to spreading the knowledge, and stimulating the desire to share knowledge affects the level of innovativeness.

The object of the study in this article is the potential of knowledge and innovation, which must be understood as all the factors affecting the ability to effectively implement projects of innovative nature. It constitutes a set of interrelated elements of resources, which, owing to the performed work, shall be transformed into a new state of affairs – with the possibilities of specific measures and forces of creating new values. Efficiency

of such actions is one of the most important determinants of shaping competitiveness of networks.

This article aims to assess the influence of knowledge and innovation potential on the efficiency of clusters. For this purpose, the results of research conducted in 2013 in 63 clusters operating in various industries throughout Poland were used.

The multi-criteria aggregate evaluation which takes into account the established patterns and evaluation criteria was used to evaluate the efficiency of the examined clusters. The linear model was used in order to examine the influence of knowledge and innovation potential on the efficiency of the examined clusters.

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Aim and object of the study

The aim of the conducted studies was to evaluate the influence of knowledge and innovation potential on the efficiency of the examined clusters. The hypothesis of the existence of a correlation between the formation and growth of the knowledge and innovation potential and the efficiency of the clusters was the starting point here. This hypothesis implies a significant impact of the knowledge potential and the innovation potential of clusters on their efficiency.

Clusters and cluster initiatives operating throughout Poland were the object of the study. A cluster is a kind of a network having some distinctive features. Most authors [13;14; 12; 9; 15] stress in various ways that a cluster is an aggregation (group) of entities (usually economic entities) operating within a single sector (similar sectors), which are located in close geographical proximity (in one geographical area) and cooperate closely with one another. Moreover, clusters enable creating the effect of synergy cooperating under the same market principles, collaborating and creating value within the supply chain [13]. A common feature of aggregations referred to as clusters is their presence in the specified geographical proximity of interconnected companies, specialised suppliers, subcontractors and service providers, companies operating in related sectors, and other institutions of a different kind (for example, universities and other research entities, standardisation bodies, and industry associations). These entities both compete with each other and cooperate in some areas [20]. Clusters are defined here as a system of relationships (connections) of an external and/or internal nature between the network components i.e. employees or organisational units (e.g. departments, divisions) and/or independent entities (e.g. enterprises, organisations). In practice, this means connecting elements of various organisations and institutions to create different network combinations (as required), and their number and character are determined by the number and type of relations taking place between the network components [1].

Table 1 presents the characteristics of clusters constituting the object of the study across three criteria: industry, scope of activity, organisational and legal form.

Table 1. Identification of the object of the study across the selected criteria

No.	Criterion	Percentage of examined clusters
	Industry	(%)
1.	energy	5
2.	construction	7
3.	food	6
4.	aviation	4
5.	ICT	10
6.	environmental protection	9
7.	IT	18
8.	telecommunications,	15
9.	eco-energy	2
10.	multimedia	3
11.	waste management	4
12.	chemistry	1
13.	polygraphy	3
14.	maritime industry others	1
	Range of activity	(%)
1.	regional	59.26
2.	national	18.52
3.	international	18.52
4.	global	3.7
	Organisational and legal form	(%)
1.	association	28
2.	partnership agreement	27
3.	consortium	18
4.	agreement	24
5.	informal cooperation network	2
6.	limited liability company	2

Source: Own study based on the conducted research.

Multi-criteria evaluation of the efficiency of clusters

One of the most important reasons to create a network of organisational networks and also an interesting research prospect is to consider this process in terms of efficiency. The review of the literature indicates that although the issue of the network is heavily exposed in it, as yet relatively little research is devoted to measuring efficiency of networks. This issue has not found a suitable place in the theoretical and practical investigations despite its undoubtedly high significance.

The efficiency of an organisation is a multi-dimensional concept. Contemporary researchers dealing with the problem of efficiency indicate the need for simultaneous use of both the purposive and systemic approach in the evaluation of the organisation efficiency. Such views are reflected in the contemporary interpretations of the efficiency

concept, as a "category of evaluation of an organisation." According to RM. Steers [19], one of the major Western researchers dealing with the issue of efficiency, organisational efficiency can be defined as the ability of the organisation to achieve and implement its operational objectives. Such a broad approach to the efficiency requires considering it in different dimensions and at different levels of aggregation, using both the quantitative and qualitative criteria.

The multi-criteria aggregate evaluation taking into account the established patterns and evaluation criteria was used in the present article to evaluate the efficiency of the examined clusters. In the case at hand, the aggregate evaluation is a part of the methodology of diagnostic analysis focused on the examination of the performance (efficiency) of the cluster.

The proposed methodology for evaluating the efficiency of network structures involves the possibility of carrying out the multi-criteria evaluation of this efficiency. The multi-criteria evaluation of this phenomenon in different objects becomes possible when transforming values of the original features in order to standardise them. The transformed variables are free of changes and take the values of similar order of magnitude. Methods for the transformation of values of the original diagnostic features are referred to as the normalisation methods. The standardised values of diagnostic variables may be subjected to the aggregation process, which results in obtaining a synthetic (aggregate) variable characterising each object due to the evaluated complex phenomenon. Knowledge of the evaluations of objects enables to construct their ranking, i.e. the system, in which the objects are sorted in order from the best to the worst due to the synthetic variable value [8].

Aggregate evaluation is a method which is characteristic for different types of diagnostic analysis methodologies (evaluation methodologies). According to A. Stabryła [17], the essence of the aggregate evaluation is to determine the synthetic value of the organisational status and functioning of the organisation on the basis of merging the individual evaluation criteria into one. This process constitutes a derivative of the multifaceted approach, since for merging different comparative aspects (dimensions, perspectives) into one whole, it is necessary to indicate the appropriate assessment criteria. A characteristic distinguishing mark of the aggregate evaluation is the principle of merging individual criteria in order to obtain answers to the question of overall value of the examined object. In this sense, the aggregate method may be used as an auxiliary element for conducting the assessment of the organisational network efficiency.

The fundamental methods of the aggregate evaluation include: ranking, scoring, and quotient normalisation. Moreover, under the aggregate evaluation, it is also possible to indicate the methods related to weighing of evaluation criteria, ranking, and categorising the objects (e.g. organisational networks or entities within networks).

The universal concept of the aggregate evaluation is the analysis of preferences, which is a research approach involving classifying the objects in a specific scale, which is reflected in the hierarchy of importance of the objects [16]. Analysis of preferences includes both the process of evaluation and the process of verification of the scores received . The overall objective of this approach is the multi-criteria aggregate evaluation, which can be focused both on analytical and comparative studies, and the selection of variant solutions.

The cycle of the research process appropriate for the discussed method comprises the following steps:

- determination of the structure of the evaluation criteria,
- qualification of the evaluation criteria
- verifying evaluation and categorisation of company's achievements.

The primary objective of the conducted study was:

- evaluation of the efficiency of the examined clusters using the selected criteria (synthetic and partial) and the patterns of evaluation divided into generic groups,
- categorisation of the examined clusters (classification of individual clusters to the categories indicating the gradation of the validity of the calculated efficiency index).

Determination of the structure of the criteria for the evaluation of organisational networks efficiency

At this stage, the selection of diagnostic measures which in this case are used to determine the actual state was carried out. The evaluation criteria are the characteristics or parameters of the axiological (evaluative) nature.

In the comprehensive classification of activities of the organisation, the structure of the evaluation criteria should be diverse but it is also appropriate to take care of the complementarity of individual criteria. The main problem at this stage is to determine the type and number of the criteria. Generic and quantitative selection of the evaluation criteria is made on the basis of the two steps of the research procedurę [5]:

- first selection of the evaluation criteria. It involves the division of criteria into a) relevant, b) side, and therefore unimportant or irrelevant,
- division of the relevant evaluation criteria into generic groups (this step expresses the essence of determining the structure of the evaluation criteria).

The set of criteria for the efficiency evaluation of the examined clusters is presented in Table 1. They were divided into the following type groups: (1) economic criteria, (2) structural criteria (3) criteria concerning knowledge management and organisational learning, (4) innovation assessment criteria, (5) social criteria.

Synthetic and partial criteria presented in Table 2 were analysed in particular generic groups. In this case, the selection of the criteria is determined by the object of the study. Determination of the values of the individual criteria was performed through assigning them the properly selected range of questions in the questionnaire used in the study.

Table 2. The set of criteria and models used for the multi-criteria aggregate evaluation of the examined clusters

Generic groups of criteria	Synthetic criteria	Partial criteria	Patterns
Group 1. Criteria for the evaluation of the network structure efficiency (economic dimension)	K1. Productivity account	structural productivity	- productivity indicators P and Pi greater than 1 (the activity generates profit)
	K2. Indicators of productivity of assets in total	indicators of productivity of assets in total	- the indicator value increases over time, e.g. in comparison to the previous years (this means the desired increase in production per unit of property) - the indicator level is higher in comparison to other companies in the same industry (in this case, the model may be a company, which has the highest indicator level in the industry)
	K3. Return on sales indicators	return on sales indicator (ROS)	- the ROS indicator level is higher in comparison to other companies in the same industry (in this case, the model may be a company, which has the highest indicator level in the industry)
Group 2. Criteria for the evaluation of the network structure efficiency (structural dimension)	K4. Objectives and tasks	compatibility of objectives and operational conditions legitimacy of objectives completeness of objectives level of meeting the objectives adequacy of resources to objectives and tasks	- the objectives are adjusted to the expectations of the environment and operational conditions - the objectives are adjusted to the adopted strategy - a complete set of objectives and tasks from the point of view of the conducted activity - evaluation of the actual implementation of the objectives and tasks (no reservations) - there are no cases of failure to implement objectives or tasks due to the lack of resources
	K5. Flexibility (dynamics)	frequency of system reconfiguration variability in the number of network relationships in the time interval	- there are high standard deviation values6indicating a large variability of the system numbers in the specific period of time - variability of membership in the network is high (changes are frequent) and unplanned by the participants - there is a high variability in the number of network relationships in the time interval
	K6 Coordination	number of centres coordinating activities in the network circulation of coordination activities or the lack thereof changes of coordination centres (changes in the authorisation to the coordination): number of connections generated by the coordination centres	- number of centres initiating connections is approaching the number n (the number of network participants)7 - there is a large circulation of authorisations in the field of network coordination - there occur changes of coordination centres (changes in authorisations to coordinate): - there is a considerable number of connections generated by the coordination centres
	K7. Cohesion	presence or absence of communication gaps causing that the information or knowledge does not reach the individual network nodes number of connections between the	- there are no communication gaps causing that the information or knowledge does not reach the individual network nodes - there is a maximum number of

		nodes strength and nature of relationships between the entities relations between the active and inactive relationships	connections between the nodes (each entity (node) of the network is related to every other entity (node) belonging to the same network) - there are relatively strong, direct, intense, frequent, and positive relations between the entities; the connections between the entities are permanent - at a given moment, there is a large number of entities active within the network, which exceeds the number of inactive entities
	K8. Scale of activity	created value chain (it determines the level of diversification of activities)	- depending on the nature of activities of the entities in the network, the created value chain takes one of the following three configurations:
	K9. Network potential	access to the disseminated resources level of diversity of the units forming the network usefulness of the information systems, level of advancement of the information systems financial potential accumulation of the network resources	- network entities have access to the sources of information remaining at the disposal of other entities - there is a technical infrastructure necessary to provide access to the disseminated information resources - there is a low or extremely high diversity of the network entities (intermediate values have a negative impact on the network efficiency) - the organisation supports the following tasks with information systems: development of a new product or service, administrative services, internal communication, information processing, customer service and assistance
	K8. Scale of activity	created value chain (it determines the level of diversification of activities)	- depending on the nature of activities of the entities in the network, the created value chain takes one of the following three configurations:
	K9. Network potential	access to the disseminated resources level of diversity of the units forming the network usefulness of the information systems, level of advancement of the information systems financial potential accumulation of the network resources	- network entities have access to the sources of information remaining at the disposal of other entities - there is a technical infrastructure necessary to provide access to the disseminated information resources - there is a low or extremely high diversity of the network entities (intermediate values have a negative impact on the network efficiency) - the organisation supports the following tasks with information systems: development of a new product or service, administrative services, internal communication, information processing, customer service and assistance - the network has its own financial resources and possibilities of financing (acquisition) of financial resources - there are direct relationships formed as a result of cooperation of the company with customers, suppliers and partners

			cooperating with them - networks entities obtain indirect knowledge about potential partners (the knowledge obtained from the previous collaborators or partners of their partners)
	K10. Configuration	level of centrality	- the maximum activity of a network actor measured by the number of connections with other actors (direct connections). The maximum value of the centrality level is equal to n-1, where n is the number of networks
	K11. Formalisation	scope of formalisation	- every cell, organisational unit, network element (entity) has a full set of organisational documents, a manner and a detailed description of the principles and the scopes of activities take into account the complexity of tasks
Group 3. Criteria for the evaluation of the network structure efficiency (dimension of knowledge management and organisational learning)	K12. Sharing knowledge	sharing knowledge with co-operators sharing knowledge within the network barriers of knowledge sharing	- most of the network entities create common bases with co-operators - there is a significant degree of use of the modern technologies for improving the relations with co-operators - the network entities significantly acquire from the co-operators information necessary for improving their activities - there is a significant degree of use of the modern technologies for improving the internal contacts - the entities evaluate positively the mutual exchange of information - there are technical and organisational solutions for knowledge collection systems
			- the knowledge is collected and properly disseminated - there is a good communication - there is an extensive information infrastructure - there is an appropriate management style - there is a slight fluctuation of specialists - there is no competition between employees
	K13. Solving problems in a team	mutual contacts and use of competent staff in a particular field barriers impeding the use and exchange of the knowledge among employees participation in the design works and quality circles rewarding the results of the group work	- information on the employees having specific knowledge resources must be available at any time - there is a possibility of the mutual contact and use of the competent staff in a particular field - there are no barriers to use and exchange the knowledge among employees - there is no competition, the results of the group work are more preferable than the results of the individual work. - employees are encouraged to solve problems collectively and share ideas - employees can participate in the design works, - results of the group works are rewarded
	K14. Use of the information systems	level of use of information systems level of system function implementation in relation to the information needs of the user use of the network multimedia	- the following systems are used: transactional systems (TS), database systems, decision support systems (DSS), management information systems (MIS), expert systems (ES), intelligent decision

		use of tools supporting knowledge management	support (IDSS), early warning systems (EWS), simulation systems (DSS), artificial intelligence - the model level of the indicator is the value of 100%, meaning that the system has features that fully satisfy the needs of the user - the network uses multimedia applications related to the data transmission via complex networks (Internet, Outernet). The following are used: video conferencing, distance learning, interactive multimedia kiosks, exchange of information between the work groups, audio-visual databases, interactive information systems - the network uses most of the following tools: databases with data on the customers, products, services, technologies, markets, competitors, document flow systems, video conferencing and teleconferencing systems, Internet, web portals, e-mail
	K15. Internal communication	use of information technologies in the processes of communication knowledge of the information sources barriers to the information exchange effectiveness of communications informal information channels use of information systems to disseminate the knowledge	- used information technologies improve to a large extent the internal communication system - employees know where to find the specific information sources - there are no barriers (at the individual level and at the network level) to exchange information - there are skills at the network level,
			which can be used both by the sender and by the recipient: (1) tracking the information (which consists of checking after a certain time whether the information has been received and understood), (2) regulating the information flow (meaning that the sender or the recipient takes steps to counteract any possible information overload), (3) understanding the richness of different media (use of the different means of communication with employees) - informal circulation of information is controlled through maintaining open communication channel and rapid reactions to false information The following systems are used to disseminate the knowledge: TS, database, DSS, MIS, ES, IDSS, DSS and multimedia
Group 4. Criteria for the evaluation of the network structure efficiency (innovativeness dimension)	K16. Investment activities and expenditures	investment ratio (investment expenditures as a percentage of the revenues) expenditures on new products to the total expenditures expenditures on R & D to the revenues	- investment ratio (investment expenditures as a percentage of the revenues) takes a higher level than the average for the particular industry - indicator of the expenditures on new products to the total expenditures is at a higher level than the average for the particular industry - indicator of the expenditures on R & D to the revenues is at a higher level than the average for the particular industry
	K17. Research and development works	documentation of research and development work (patents,	Network: - Holds the patent(s) on an invention

		rationalisation works, etc.) number of the mastered production technologies and markets changes in the scope of a business strategy organisational and technical innovations market research in order to introduce a new product introduction or improvement of a product or process research works of the experimental or applied nature advanced management techniques	developed by it, - implemented the rationalisation project(s), registered the trademark(s) - mastered at least one production technology or market - implemented a new or significantly revised strategy - introduced at least one organisational or technical innovation - conducts the market research in order to introduce a new product or service - successfully introduced or significantly improved a product, service or process - conducts research and development works of an experimental or applied nature - implemented advanced management techniques (TQM, BSC)
	K18. Development cooperation	cooperation with science and research institutions cooperation with customers and suppliers seminars and scientific conferences	- companies belonging to the network cooperate with universities, research institutions (PAN), technology transfer centres, research and development institutions - network entities cooperate with customers and suppliers in order to gain knowledge to implement a new solution or to expand the scope of activities network entities participate in the seminars and conferences aiming at exchanging experiences
Group 5. Criteria for the evaluation of the network structure efficiency (social dimension)	K19. Social commitment	financial resources allocated to the social investments (by priority: sports, health, science, environmental protection) number of projects received from the social organisations to the number of the projects completed financial subsidies of a charity nature as the percentage of gross profit creating jobs	Network: - allocates the financial resources to social investments - implements the projects from social organisations - subsidises charitable activities - creates new jobs
	K20. Development of employee potential and interpersonal relationships	level of trust ability of interpersonal cooperation rewarding activities affecting the development of employees occurrence of the task teams use of the coaching method development of professional career paths extension of tasks enrichment of tasks encouraging employees to participate in management implementation of the competence development programme expenditures on trainings.	- interpersonal relations in the network have a high level of trust - there is the ability to cooperate - activities affecting the development of employees are rewarded - there are task teams - the coaching method is used - professional career paths are developed - extension of tasks is used - enrichment of tasks is used - there is participation in management - the competence development programme is implemented - expenditures on trainings are allocated (approx. 10% of the expenditures)

Source: Own work.

Qualification of the criteria for the evaluation of the organisational network efficiency

Three stages were distinguished in the following qualification procedure:

• developing the assessment standards,
• selection of preferential aspects,
• determination of ranks of the evaluation criteria.

Development of the model of object evaluation is one of the most important steps in the procedure. The evaluation model is a set of evaluation criteria forming a certain aggregate which is a multi-criteria evaluative system. The reference values presented in Table 1 were

adopted for the selected evaluation criteria. The proposed reference values become stimulants and nominants.

The next step in the adopted procedure was to determine the preferential aspects. Preferential aspects are the points of view, considerations, according to which the validity of objects is determined, prioritising them by assigning them ranks and awarding points. The ranks and points are used to relativise and schedule the objects (in the sense of relations of the majority, minority or equivalence character). Any determinants being tangible or intangible values can be adopted as the preferential aspects. Therefore, evaluation criteria of the economic, organisational, technical, etc. nature can function as the preferential aspects [16].

For the criteria for evaluation of network efficiency, the following preferential aspects were adopted: economic efficiency, competitiveness, development possibilities, flexibility, innovation.

Subsequently, the ranks of evaluation criteria were established. The ranks were assigned to the individual evaluation criteria on the basis of the three-point scale: 3 points – the dominant criteria, 2 points – the essential criteria, 1 point – the useful criteria.

The method of expert reviews was used to conduct the qualification of the evaluation criteria. The expert judgements are in this case the resultant of their own sectional opinions based on the preferential aspects [18]. The group of experts consisted of coordinators of the surveyed clusters (10) as well as external experts, including research workers (5). For the calculation of average expert rank (for each criterion) the following formula was used:

$$\textbf{(1)} \qquad SXj = \frac{\sum_{k=1}^{r} Xij}{r}$$

where:

SXj – average expert rank
Xij – rank of the j-th evaluation criterion determined by the k-th expert
r – number of experts

The implementation of the discussed procedure was carried out according to the following steps:
- selection of experts
- determination of partial evaluations of each criterion in accordance with the scale:
3 – the most significant (dominant) criterion
2 – the significant (essential) criterion
1 – the medium intensity (useful) criterion
- determination of synthetic evaluations of the specific criteria as the arithmetic averages of the partial evaluations of experts (according to formula 1)
The results of these activities are summarised in Table 3.

Table 3. The ranks of criteria for the efficiency evaluation of the examined clusters

Criteria for the efficiency evaluation	Rank
K1 – Productivity account	2
K2 – Indicators of productivity of assets	2
K3 – Return on sales indicators	2
K4 – Objectives and tasks	3
K5 – Flexibility (dynamics)	2
K6 – Coordination	2
K7 – Cohesion	1
K8 – Scale of activity	1
K9 – Network potential	2
K10 – Configuration	2
K11 – Formalisation	2
K12 – Sharing knowledge	3
K13 – Solving problems in a team	2
K14 – Use of information systems	3
K15 – Internal communication	3
K16 – Investment activities and expenditures	3
K 17 – Research and development works	3
K18 – Development cooperation	3
K19 – Social commitment	1
K20 – Development of employee potential and interpersonal relationships	2

Source: Own work.

Verifying evaluation and qualification of the examined clusters

The control assessment is supposed to indicate the extent to which a given entity respects the established requirements (expressed by the patterns of performance assessment). Interpretation of the results and their trends is essential for the correct verifying evaluation, especially in the case of use of the multi-criteria model in which individual criteria are the stimulants, destimulants, and nominants [16]. The formula of the verifying evaluation is expressed by the relationship of the actual state of the model (the model state) or is an equivalent reference of the actual state to the appropriate level of evaluation on the valuing scale. The verifying evaluation defined in such a manner is simultaneously a tool of standardisation of evaluation criteria, owing to which the aggregate evaluation is possible.

In order to carry out the verifying evaluation, the standardised five-point evaluation (Table 3) was adopted.

For each network examined, the efficiency index (EI) value was determined according to the following formula:

$$IE_i = \sum_{j=1}^{n} w_j \, q_{ij}$$

where:

w_j – rank of the j-th evaluation criterion,

q_{ij} – point verifying evaluation in relation to the i-th network,

i = 1,..., m – network,

j = 1,..., n – evaluation criteria.

Subsequently, the EI index was categorised, i.e. the value of the EI point qualification index was translated to the specific category. For this purpose, the qualification regulations, which constitute a formalised approach to the terms and conditions for determining the category of clusters, were prepared. The qualification regulations should contain provisions concerning the following issues [18]:

• construction of the evaluative scale,
• establishment of the hierarchical ranges in the evaluative scale,
• labelling the cluster categories.

Re. 1). Relative or absolute scaling can be used in the procedure of comprehensive qualification. The relative scaling refers to any numerical range (positive or negative-positive) at the maximum value of the index EImax = N, where N is a particular positive number given in advance (e.g. 100, 800, 1000). The relative scaling is determined in the range from 0 to 100% (or from 0 to 1). In this qualification procedure, the upper limit of the range N was adopted, which corresponds to the relative value of 100%. Subsequently, the verifying evaluation was carried out, in which the standardised five-point 0-4 evaluation was adopted, determining the conversion factors for the verifying evaluation. The maximum weighed point value of the efficiency index is 168. This value could have been achieved by the enterprise if it received grade 4 for each of the 20 assessment criteria.

Re. 2). For the IE index, the hierarchical ranges, which are the boundaries of qualification levels were determined. These ranges correspond to the specific categories indicating the validity gradation of the index (table 4).

Table 4. Hierarchical ranges of the EI index

Category	Scoring
E – network with a high efficiency index (the value of the IE index higher than 80% of the maximum value)	136-168
EA – network with a satisfactory efficiency index (the value of the EI index within the range of 61-80% of the maximum value)	102 - 135
EB – network with an average efficiency index (the value of the EI index within the range of 40-60% of the maximum value)	57 - 101
EC – a network with a low efficiency index (the value of the EI index from 40% of the maximum value)	0 - 56

Source: Own work.

Re. 3) Designation of the categories of the examined clusters was the closing stage of the categorisation. At this stage, there was a calculation of the EI index for each i-th cluster and assigning the particular category to it. The table shows the number of clusters classified to the appropriate categories (Table 5).

Table 5. Number of the distinguished cluster categories in the study of the EI index

Category	EI index value	Number of clusters
E	168-128	-
EA	127-87	18
EB	86-46	45
EC	0-45	-

Source: Own work.

When analysing Table 4, it can be noticed that none of the studied clusters was qualified as category E meaning a network of high efficiency index, or category EC meaning a network of low efficiency index. The largest number of clusters (45) are clusters of average performance index, whereas the EA category (satisfactory level) included 18 clusters.

Methods for achieving high efficiency among the examined clusters are characterised by an average or satisfactory level of flexibility, innovativeness, knowledge management, proactivity, and, finally, social commitment in the examined clusters. Most frequently, the respondents defined the productivity level of clusters as average (42.86%) and high (32.14%). Clusters with a high efficiency index pay a lot of attention to the strategy creation and possession of a vision for the development. As for the objectives in the case of this cluster category, the responses indicated predominantly that they are adjusted to match the environment expectations and the operating conditions, as well as the adopted strategy, and the set of goals and objectives is complete from the point of view of the conducted activity. This cluster group can be referred to as value-oriented, as they all have a strong organisational culture based on the key values, such as honesty, reliability, commitment, trust, satisfying customer needs. These values are communicated inside and outside the cluster (to the stakeholders), which helps maintain good relationships with the external stakeholders. There is also a distinct awareness among the respondents of the importance of trust in the cooperation within the clusters and with the external stakeholders. The respondents evaluated the impact of trust on the result of cooperation within the cluster as large (41%) and very large (14%).

Leaders play an active role in the examined clusters. According to the respondents, the most important competencies of the leaders are: attracting new entities, creating a vision and developing strategies, as well as integrating the activities of the partners. Secondly, according to the respondents, the leaders stimulate the processes of knowledge management and the innovative processes. The result of such an approach is a high level of trust in the cluster leaders.

As for the human resources management in the examined clusters, it is possible to notice a high level of empowerment. This phenomenon is rather informal, it is not a conscious method of people management, but a subconscious and intuitive way to maintain the leaders. Employees have a positive attitude to work, they evaluate it as something valuable. They are also strongly convinced that they possess the professional competence. Generally, there is an atmosphere of trust and justice. The examined clusters (especially those with a satisfactory level of efficiency) had a good image among the local communities. Especially noteworthy in this context is their social commitment.

Study of the influence of knowledge and innovation potential on the efficiency of clusters

On the basis of the conducted studies, it was possible to assess the knowledge and innovation potential for the same sample of studied clusters. The primary objective of the conducted study was:

• identification of the scope of application of knowledge management and organisational learning in the studied clusters.
• assessment of the degree of fulfilling the functions of knowledge management and organisational learning in the studied clusters.
• assessment of the innovative potential of the studied clusters

Assessing the knowledge and innovation potential was based on the assessment criteria from two type groups: group 3 including the knowledge management and organisational learning criteria of assessment, and group 4 including the innovation assessment criteria.

The value of the knowledge and innovation index (KII) was determined in a way analogous to the efficiency assessment of the studied networks, and subsequently, for the KII index, the hierarchical ranges, which are the boundaries of qualification levels were determined. The maximum weighed point value of the KII index is 72. This value could have been achieved by the cluster if it received grade 4 for each of the 8 assessment criteria (Tab. 6).

Table 6. Hierarchical ranges of the KII index

Category	Scoring
W – network with a high potential of knowledge and innovativeness (the value of the KII index higher than 80% of the maximum value)	57 - 72
A – network with a satisfactory potential of knowledge and innovativeness (the value of the KII index within the range of 61-80% of the maximum value)	45 - 56
B – network with an average potential of knowledge and innovativeness (the value of the KII index within the range of 40-60% of the maximum value)	28 - 44
C – network with a low potential of knowledge and innovativeness (the value of the KII index from 40% of the maximum value)	0 - 27

Source: Own work.

Table 7. Number of the distinguished cluster categories in the study of the KII index

Category	KII index value	Number of clusters
W	57 - 72	-
A	46 - 56	22
B	27 - 45	33
C	0 - 26	8

Source: Own work.

$$y_i = \alpha_0 + \alpha_1 x_1 + \varepsilon_i$$

where: y_i represents the number of points evaluating the efficiency for the i-th cluster, x_i represents the number of points determining the innovative knowledge potential for the i-th cluster, it represents the parameter standing by the independent variable and finally – the value of the random component for the i-th cluster.

Among the studied clusters, none received category W, i.e. a cluster of an excellent knowledge management level and high knowledge and innovation potential. Most of the studied clusters are classified as A (22) and B (33), which proves the satisfactory or average knowledge and innovation potential. In the group of clusters with a satisfactory knowledge and innovation potential level there were mainly clusters operating in IT and telecommunications, and the area of high technologies.

In the course of further proceedings, the question of the relationship between the knowledge and innovation potential and the efficiency of the examined clusters was

asked. It was assumed that there are correlations between those variables. The following hypotheses were verified:

1. there are links between the creation and growth of knowledge resources and the efficiency of the examined clusters,
2. there are links between the innovative potential of the examined clusters and their efficiency.

To examine the impact of the knowledge and innovation potential on the efficiency of the examined clusters, the variable efficiency (EI — dependent variable) expressed in scores and the knowledge and innovation potential variable (KII — independent variable) also expressed in scores were used in the study.

To describe the formation of the dependent variable (IE), the linear, exponential, and power models were proposed. On the basis of the analyses, it turned out that the best-matching model to the empirical data is the linear model (the highest determination coefficient) in the following form [11].

Table 8. Evaluations of the parameters of the linear model of efficiency (EI) depending on the knowledge and innovation potential (KII)

Specification	Alpha	Standard error	t(61)	p-value
Free term	44.6440	3.2872	13.5810	0.0000
KII	1.1972	0.1001	11.9570	0.0000
Adaptation of the model	$r=0.8372$; $R^2= 0.7009$; corrected $R^2= 0.6960$; $F(1,61)=142.97$ $p<0.0001$			

Source: Own calculations.

The calculated Pearson factor of the line correlation ($r=0.8372$) indicates a strong linear relationship between the variables. The estimated model turned out to be well matched to the empirical data since 70% ($R^2 = 0.70$) of the variability of the dependent variable (EI) was explained by the variability of the independent variable (KII). The positive parameter standing by the independent variable means the positive influence of knowledge and innovation potential on the efficiency of clusters. The increase in the evaluation of the KII by one point causes the increase in the efficiency evaluation by an average of 1.1972 point (Table 8).

The study of the cluster group showed a strong correlation between the creation and growth of knowledge resources and the efficiency of the examined clusters and between the innovative potential of the examined clusters and their efficiency. This confirms the adopted hypotheses of the relationship between the knowledge and innovation potential and the efficiency of the examined clusters.

Summary

The starting point for the conducted studies was the supposition of the existence of a correlation between the creation and an increase in the knowledge potential and the innovation potential, and the efficiency of network structures. The adopted hypothesis implies a significant impact of the knowledge potential and the innovation potential of an organisational network on its efficiency.

The aggregate evaluation presented in this article enabled us to determine the aggregated efficiency index (EI) for each of the 63 examined clusters, and, subsequently, to categorise them. The aggregated index (KII) measuring the knowledge and innovation potential in the examined clusters was also calculated, and the categorisation of the clusters by KII index was conducted.

The statistical analysis revealed a significant influence of the knowledge and innovation potential on the efficiency of the examined clusters. This confirms the adopted hypothesis that the potential of knowledge and innovation is one of the main determinants of the efficiency of network structures.

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