A Mapping for Managers: Open Innovation for R&D Intensive SMEs in the life sciences sector

Abstract

Purpose
The study examines what strategies the CEOs of Research & Development (R&D) intensive Small/Medium Enterprises (SMEs) in the life sciences sector carry out in regard to open innovation (OI), as R&D costs continue to rise, placing pressure on innovation managers.

Design/methodology/approach
A qualitative study was carried out, consisting of 30 semi-structured interviews with CEOs of small R&D intensive SMEs in the life sciences sector. We analysed the key factors identified by the CEOs in relation to their OI strategies.

Findings
SMEs adopt a range of OI strategies and collaborations, subject to certain conditions. A multilevel mapping developed from the analysis connects actors to the wider domain, setting the outcomes of the research in context.

Research limitations
This qualitative study provides detailed understandings that could provide the basis for a wider quantitative study that would provide greater coverage of the sector, thus reinforcing the outcomes.

Practical implications
The study will be relevant to practising CEOs who are considering the range of options offered by OI.

Originality/value
While large firms are adopting OI strategies, less is known about the OI strategies developed in SMEs. The study addresses that gap. The life sciences context is also novel.

Key words: Open innovation, SME, R&D intensive, life sciences, strategies, CEOs

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Perceptions of Open Innovation for R&D intensive SMEs in the Life Sciences sector

1. Introduction (shortened and some material including the first para of the old version place in the lit review)

As Oakey (2013) points out, innovation is widely acknowledged as a key element of success for firms ranging from the very smallest to the largest multi-national enterprises. Since the introduction of Open Innovation (OI) as a concept (Chesbrough (2003a), several studies have identified and examined the different conceptions of openness relating to the structuring of the

innovation process (Dahlander and Gann, 2010; Herzog and Leker, 2010). It is argued that exploiting external knowledge is a critical component of innovative capabilities (Cohen and Levinthal, 1990) as it is becoming too expensive to have all innovation competencies in-house (Chesbrough 2003a; Chesbrough, 2010; Chesbrough *et al.*, 2006; Dahlander and Gann, 2010). Thus, the OI activities of large companies and corporations such as P&G, Intel and IBM have been studied extensively in the literature (Chesbrough, 2003a, 2003b, 2006; Mortara and Minshall, 2011). There is growing evidence that OI can impact firms' performance positively though some authors have questioned Chesbrough's claims for OI, mainly for its lack of novelty (Trott and Hartmann, 2009), and also for its lack of applicability to certain contexts (Oakey, 2013). As Dąbrowska *et al.*, (2013) have argued, there is also still a need to better conceptualise and explain OI, particularly for practitioners.

Although SMEs are agreed to play a key role in innovation generally, to date, only a limited number of studies have examined OI activities in SMEs (Brunswicker and Vanhaverbeke, 2014; Lee *et al.*, 2010; Parida, *et al.*, 2012; Pullen *et al.*, 2012; Spithoven *et al.*, 2013; Van de Vrande *et al.*, 2009; Hossain, 2015). Thus, in this paper, we examine 30 SMEs from the life sciences sector, all reliant for survival on R&D intensive activities around the management of IP portfolios. The sector is particularly relevant as it needs to boost its innovation performance to combat high R&D costs. It is dominated by large companies that have tended to concentrate on core competencies evolving around key technology platforms and therapeutic areas, combined with creating collaborations with the right partners (Fredberg *et al.*, 2008), including the adoption of OI strategies that target patent-rich SMEs (Von Stamm, 2004; Hunter, 2010, Mullard, 2012). Such SMEs are a vital part of the life sciences sector as they are often responsible, as new ventures or spin-outs for bringing new science (drugs, devices and clinical processes) to the attention of the market. Yet we know little about how they operate their innovation in a sector dominated by the global companies. This study contributes to this gap, investigating what OI strategies are used and how they fit into the wider sector context. We are informed by the CEOs, who are best placed to provide insight into the strategies and

approaches adopted by such firms. The paper begins with an overview of the literature, followed by the methodology, then results, conclusions, limitations and suggestions for further research.

2. Literature Review

The context for our paper is the life sciences sector which provides a dynamic view of R&D intensive industries. Overall, innovation in the life sciences sector is considered a critical element of business productivity and competitive existence (Zaltman *et al.,* 1973; Omachonu and Einspruch, 2010), but can be an extremely complex, expensive and risky process (Euromonitor, 1988; Gurau, 2004; Saviotti, 1998; Senker, 1998), particularly for SMEs. The early innovation model for the industry has been described as a linear and internally focused, or closed process (Figure 1), where a sequence of activities were driven either by basic advances in knowledge, social, or economic opportunities that provided an incentive for risk-taking investment to seek for new solutions (Attridge, 2007, p. 220; Gambardella, 1995).

Insert Figure 1 about here

This model became established in an environment of highly intensive R&D, regulation and legislation where the firm's activities were part of an overarching context that yielded vast social benefits. However sustaining innovation output in this way demanded huge research funding, combined with massive marketing expenditure, as integral features of the innovation process for such products were tending to become more fragmented, leading to an increased risk of market failure (Comanor and Scherer, 2013; Hara, 2003; Malerba and Orsenigo, 2002, p. 667-8).

Despite challenges from rising R&D costs, the life science sector remains robust. In 2014, it attracted an additional £2.5bn in R&D funding from the year before, and overall, the UK sector consists of more than 4,398 companies, employing over 183,000 people and generating a £56bn in turnover (Strength and Opportunity, 2014). Yet, it has been suggested that the sector is suffering from a productivity crisis as the cost of R&D increases and additionally, the changing regulatory

environment, becomes more stringent, with an increasing focus on safety and efficacy (Hara, 2003; Lowman *et al.*, 2011; Paul *et al.*, 2010; Munos, 2009; Light and Lexchin, 2012; Subramaniam, 2003; DiMasi *et al.*, 2003; Melese *et al.*, 2009; Kaitin and DiMasi, 2011; LaMattina, 2011; Schuhmacher *et al.*, 2013). In addition, despite the large investments, merges and acquisitions, the sector has faced marked decline in productivity, as the size of the company or R&D budget does not necessarily guarantee equivalent success (Comanor and Scherer, 2013; Khanna, 2012, p. 1089). The traditional linear approach to innovation has thus come under pressure (Attridge, 2007; Altshuler *et al.*, 2010; Cohen *et al.*, 2004; Hara, 2003), although these and other imperatives for change have arguably been present since the 1980s, according to Drews (2000). The traditional linear approach is criticised as it continues to be, in essence, an exercise in trial and error.

As costs and risks have increased, and the need to better understand health care requirements in their social context is getting more complex, large life science companies have had to re-evaluate their business models to seek wider opportunities to gain access to better tools, technologies and ideas (Hunter, 2010, p 87; Lichtenthaler, 2011; Light and Warburton, 2011; Moon *et al.*, 2012). Thus, OI approaches, as initially conceived by Chesbrough in 2003, have a natural resonance for large firms; although large firms still focus on their in-house R&D activities, they have also begun to draw more extensively on discoveries, tools and target compounds which have been licensed-in from smaller firms (Danzon, 1999; Gassmann and Reepmeyer, 2005). Chesbrough argues that by acting in this way, firms can capture or create value from new technology, either by integrating a new technology in their current business approach, or by engaging into new ventures that exploit their technology in new commercial ideas (Chesbrough and Rosenbloom, 2002). This is in contrast to earlier ‘closed’ innovation models, where firms actively protect their patents and IP, trying to leverage value from their own innovative endeavours alone (Chesbrough, 2003). OI approaches also encourage firms to share their unused ideas with others (Chesbrough 2007a; Burcharth *et al.*, 2014; Hung and Chou, 2013).

(some upgrading and better phrasing in this section) It has been argued that the innovation process in the life sciences industry has always been influenced by long business cycles, multiple stakeholders and complex interactions and collaborations (Attridge, 2007; Glass and Poli, 2009). This is now the case as the current eco-system for research and development of new medicines does not adequately meet the needs of the world's population therefore making it politically and financially unsustainable (Moon *et al.*, 2012). Nonetheless, large life science firms have changed their processes and strategies towards a more open approach to innovation management, in an attempt to protect or develop their competitive advantage (Chiaroni *et al.*, 2009). Such strategies include embracing new skills based on inter disciplinary collaboration, as well as developing specific and core competences for managing the process across a global range of contributors. This networked approach evokes Rothwell's (1992) fourth generation highly networked model of innovation (Attridge, 2007, p. 221). As the innovation focus has shifted to external ideas, big life science firms have been looking to small companies for new IP, seeking partners to evaluate, utilise and acquire knowledge successfully (Arora and Gambardella, 1994; Oakey *et al.*, 1990; Sabatier *et al.*, 2010, p. 3), although the extent to which this is new, or consistently applied across companies has been questioned (Trott and Hartmann, 2009; Dąbrowska *et al.*, 2013).

Overall, SMEs do play a key role in industrial invention, innovation, economic development and subsequent technological progress (Freeman, 1982; Oakey, 2007; Rothwell and Zegveld, 1982; Roberts, 1991). If OI is being extensively adopted by large firms (Chesbrough, 2003a; 2007b; Chesbrough *et al.*, 2006; Gassmann *et al.*, 2010; Hunter, 2010), this might imply that there should be a corresponding increase in 'open' activity in SMEs, which have also felt industry pressures, yet have the opportunity to capitalise on their adaptability and flexibility. For small life science companies, which constitute 93.75 percent of UK life science companies (Strength and Opportunity, 2014), it has become virtually impossible to effectively and efficiently manage the innovation process within the firm's own boundaries, mainly due to the high number of scientific and technological competencies that cannot contemporaneously be understood to the requisite level

(Chiaroni, *et al.,* 2008; Alegre *et al.,* 2013; Chung *et al.,* 2006). Overall, the sector is becoming more complex over time, with more spin-offs from larger corporations. Building a network of inter-organisational R&D collaborations across different actors (such as start-up companies, established firms across the life sciences range, universities, research centres and science parks) can contribute to the innovation process with its particular competencies and technological assets, that are strategically necessary (Chiesa and Toletti, 2004; Niosi, 2003; Powell *et al.,* 1996). Of course, this increases management complexity overall, as in this context, the management of technological competence needs must address the formation of certain types of internal horizontal structures such as project management and virtual R&D workgroups, alongside the establishment of a collaborative working relationships with scientific partners, clients and suppliers (Quélin, 2000). However, thus far, surprisingly little emphasis has been placed on this challenging aspect of management for SMEs in this domain.

Van de Vrand *et al.,* (2009), drawing on a study of 605 innovative SMEs in the Netherlands concluded that SMEs across a range of sectors were practising OI, in line with Lichtenhaler (2008) who examined medium, as well as large manufacturing enterprises. These studies found that practising SMEs combined technology exploitation and exploration, focussing mainly on market-related targets, and call for more research into specific motives and challenges. It has been argued that OI works as an alternative to acquisition between large firms and SMEs as larger firms can access and scale technologies from smaller firm early, in an effort to gain access to specific expertise (Golightly *et al.,* 2012, p. 38). Lee *et al.,* (2010) focussed on the role of intermediaries for 2414 Korean SMEs, highlighting the networked nature of OI practice. Brunswicker and Vanhaverbeke, (2014) survey the search strategies of European SMEs and link these to firm management practices after Cohen and Levinthal (1990).

While these studies show considerable adoption of OI practices in SMEs, most of the studies are not sector specific (Lee *et al.,* 2010; Van de Vrande *et al.,* 2009; Spithoven *et al.,* 2013; Brunswicker and Vanhaverbeke, 2014). Yet sector may be important, as Oakey (2013) argues

convincingly for the case of high-technology small firms (HTSFs), which he claims have always practised openness while recognising the merits of closed systems too, for specific reasons linked to firm size and intellectual property (IP) management (Pullen *et al.*, 2012; Parida *et al.*, 2012).

Strategies in SMEs are usually closely aligned to specific business models (Casadesus-Masanell and Ricart, 2010), where the use of purposive inflows and outflows of knowledge is a vital element of innovation acceleration (Chesbrough, 2003a; Brunswicker and Vanhaverbeke, 2014) and thus competitiveness. In this sector, strategies are choices senior managers make, that shape and direct a firm's learning process around a particular technological direction, in accordance with key competences, as they are systematically associated with the strategic action of the organisation (Bierly and Chakrabarti, 1996; Glass and Poli, 2009, p. 206; Spithoven *et al.*, 2011). This occurs since product innovation drives organisational restitution by exploiting and exploring firm competences (Danneels, 2002, p. 1095-96). Senior managers therefore, are critical to a firm's outcomes because of their decisions, which ultimately account for what happens to the organisation (Hambrick, 1989, p 5; Vera and Crossan 2004, p. 222). The strategic leadership within a firm, typically exercised through the role of a CEO, plays a significant role in making all the necessary investment and operating decisions; as the managerial competence of the owner manager or the entrepreneur is a crucial factor in the long term survival and success possibilities of SMEs (Ottewill *et al.*, 2000, p. 246). Thus, we chose CEOs of our firms as participants in the research as they are best place to inform us as to what strategic choices are made.

In addition, recognising the connectedness of the many inter-related elements in the sector (Attridge, 2007), we took care to question how the strategies were fitted into the broader structure in the sector, given that innovation is determined by factors operative at different levels (Srholec, 2011; Dopfer *et al.*, 2004; Vanhaverbeke and Cloodt, 2006, p. 276; West *et al.*, 2006, p. 287; (Quelin, 2000) Building on the framework in Figure 2 (Chesbrough, 2006), we developed Figure 3 to frame our study for the specific life sciences industry context. Taking into account, we believe that OI should

be examined at different levels, through the inclusion of the various elements that create these underlying conditions.

Insert Figures 2 and 3 about here

Overall then, our study contributes to knowledge through its focus on SMEs, an underserved area, from the point of view of a specific, but very important area, life sciences. We focus on CEOs identification of strategies as these shapes the firm. We also examine challenges (after Van de Vrande, 2009) and finally, take account of context through a multilevel mapping exercise, to aid practitioner understanding of the sector (after Dabrowska, *et al.*,2013).

4. Methodology

Thus far, most studies have approached OI from a positivistic or quantitative standpoint, notably Laursen and Salter, (2006); Dittrich and Duysters, (2007); Lichtenthaler, (2008) and Verbano *et al.,* (2013). Lichtenthaler (2008), through a cluster analysis, explored the extent of external technology exploitation. Laursen and Salter (2006) explore the innovation process inside firms using regression analysis; Verbano *et al.,* examine determinants in Italian SMEs; Dittrich and Duysters, (2007) with the use of quantitative approaches, examine OI strategies in Nokia's new product development. Others have taken a qualitative approach: Chesbrough (2003a) based his arguments through a series of interviews with managers in firms struggling with their innovation process, as do Spithoven *et al.,* (2013). Dodgson *et al.,* (2006) utilised an inductive paradigm to investigate OI in Procter and Gamble's Connect and Develop; others have applied grounded theory, to investigate the behavioural reasons responsible for innovation growth (Herzog 2008), and the challenges of OI (West and Gallagher 2006). Huizingh (2010) notes the prevalence of case-based descriptive research in OI, and like Hossain (2015) calls for more explanatory studies, particularly those that take account

of context. In addition, O'Connor (2006) utilised a longitudinal cross-case approach with the use of interview methods in a study to investigate the open and radical innovation in large established firms.

4.1 Participants

The empirical data has been generated through semi-structured interviews with CEOs of 30 SMEs[1] from the UK life science sector that are registered members of the ABPI (Association of the British Pharmaceutical Industry) and the BIA (BioIndustry Association). The study utilised a purposive sample derived from personal connections and snowballing. This enabled us to use a selection of individuals that were not only willing, but knowledgeable enough to answer our questions effectively (Saunders *et al.,* 2009, p. 237). The size of the participating firms was typically 25-30 employees, though there were outliers (1 and 150 employees). They were 5-10 years old, engaged predominantly or exclusively in discovering and developing new molecular entities. Half the firms described themselves as working in pharmaceuticals, the rest were evenly spread across biotechnology, diagnostics, devices and pharmacokinetics. All the participants in the research were CEOs or senior management team members/founders able to actively discuss the strategies and practices SMEs, and thus adequately judge if, when and how innovation processes and progress had developed or occurred over time.

4.2 Data Collection and Analysis - methods

The interviews were conducted at the interviewee's work place, and were recorded and transcribed. Each interview lasted approximately one hour. We opted to use a deductive, theory driven approach to the analysis to enable us to systematically address the relatively large amount of data from the interviews, and the wide range of topics that cover the strategy domain. We used categories derived from Chesbrough (2003b), identifying strategic approaches as per the focus of this

[1] Definition of SME from: Library - House of Commons, (2014), Small businesses and the UK economy

study, but also deepening the discussion through consideration of collaboration behaviour, implementation pathways, barriers towards OI implementation and IP issues. While this approach enables a strong focus and a rigorous approach to the data, there is the limitation that emergent categories are missed, but the breadth and depth of the categories chosen guarded against this happening, as did frequent reading/re-reading of the data to ensure that we did not do so. In developing our analysis, we used Nvivo software to identify key words and phrases in the transcripts from which we derived our outcomes; an example word/phrase table for collaboration behaviour is shown in Appendix 1. The following section contains a detailed analysis of the interviews, in accordance with the five key areas: strategic approaches; collaboration behaviour; implementation pathways; barriers towards OI implementation; IP issues. Where necessary, more comment is provided on the analysis.

5. Results

5.1 Strategic approaches of SMEs

The firms' innovation strategies are determined by CEOs during the R&D activities of their firms and these specific attitudes are shaped by internal or external innovation processes, and internal or external entities, as reported in Table 1. As a result of our analysis we were able to identify four strategic approaches utilised by the participating SMEs in relation to these factors.

Insert Table 1 about here

The majority (22) of respondent firms are driven by an innovation process development approach, targeted at sector-specific venture capital funds for a specific product line. In this approach, CEOs stressed the importance that "*the innovation process development is kept in-house*" (SME-10). Here, it is evident that expansion is driven primarily by the development of the firm's technological portfolio, and effectively a closed system is operated. At the other end of the spectrum, more open pathways are applied. Some firms follow a networked innovation approach where there is a high

degree of outsourcing and collaboration. This can occur in different ways. For example, to avoid the cost of complying with the regulatory authorities, firms may transfer the test phase to other organisations and institutions through third party agreements, thus saving valuable time and resources that can be invested in other projects. It is evident that such companies are also diversifying their portfolios by allowing organisations, firms and institutions to work with them, and allowing their collaborators to ally new ideas with them. Thus, firms save valuable time in the development phase and also bring in expertise that can take the firm forward. As one CEO stated "… *we are looking at companies for in-licensing, out-licensing, or working with collaborators as a circular process*" (SME-21). Additionally, they may further seek to "*develop a network with individuals from universities, such as academics, PhD students, knowledge brokers and also external chief scientific officers, which can assist on the research and development process*" (SME-21/28) by bringing ideas and clinical information to the pre-clinical test phase. Alternatively, from an open perspective, a small number of SMEs had adopted a lead user innovation approach whereby the decisions of CEOs are driven by necessary and dependent relations with specific customers, through the development of new ideas in terms of both productivity and technological advance (SME-29/30). Such firms take into account the necessary inputs and comments of their clients, ranging from individuals to large biopharmaceutical firms who will utilise their products or technologies. With this approach, firms are in constant communication with their clienteles, but in confidential circumstances where the lead users are effectively "*brought into the fold*". Finally, there is the sector innovation approach where firms are established around the need for compliance with sectoral change around the adoption of new regulations. Such firms are influenced by changes in the industry in a form of necessary and dependent relations, as they have to adopt and comply with the statutes drawn up by medical and regulatory issues.

This pattern of results, with a mix of open and closed approaches is broadly consistent with complementary studies in the literature, for example Trott and Hartmann (2009), Dahlander and Gann, (2010), Oakey, (2013) and Dąbrowska *et al.*, (2013) who also note OI practices are not necessarily carried out under that banner. The decisions underlying choice are contingent on the

demands of maintaining IP integrity for future rounds of funding; the availability, competence and trustworthiness of potential lead users; the richness of the firm's context (such as in proximity to a university or science park for example, where partner firms and suitable lead users are more likely be found easily). While in principle, the CEOs exercise some degree of choice, the initial decisions around the firm's creation tend to set strong path-dependent trajectories from the outset.

5.2 SME Collaboration Behaviour

The sector has been cited as an example of technological collaboration and competition (Arora *et al.,* 2004; Hara, 2003; Hunter and Stephens, 2010; Paul *et al.,* 2010), where collaboration is seen as an efficient way of accessing additional or complementary resources that can speed up the exploitation of a business area (Teece, 1986; Arora and Gambardella, 1994). A polar plot of the analysis of interview responses reveals a number of interesting facets of the collaboration and partnering priorities of SMEs, in approximate order of their assigned priority (Figure 4).

Insert Figure 4 about here

- **Inter-SME partnering** was important, as the main partners of SMEs are other SMEs, not big pharmaceutical firms.
- **National government** plays a significant role in the UK, through the agencies such as the Technology Strategy Board (TSB) (now known as InnovateUK), the Medical Research Council (MRC) and the National Health Service (NHS), who all sponsor SME partnerships with other SMEs and universities, with some cases of international government partnering UK SMEs in that way, through EU programmes, for example. In several cases, the TSB and the MRC were seen as a way of continuing the firm's current projects, through matching the firm's resources. Although EU funding programmes may offer possibilities, not many UK SMEs can be reluctant to participate in them. The main barrier for firms not partaking in the EU projects is that they are administratively time

consuming, while in the UK, government agencies have already an established reputation that their collaborative programs perform successfully.

- **Academic groups and universities:** Both are significant, but academic groups appear to play a more significant role than the universities *per se*, particularly where SMEs had been established by academics who then went into the industry, and remain connected with various academic groups rather than the university itself. Of course, there are some very fluid boundaries in this space.
- **Large life science companies**, perhaps surprisingly in relation to the prevailing assumptions underpinning OI practices, are not seen as the key partnering organizations, although the OI programmes of big pharma companies suggest they welcome such collaboration. Reasons for this include wariness of SMEs towards such dominant players, combined with the inexperience of the personnel responsible for the SME's strategy. This might be explained as the lack of a critical core competency, as, finding the right partner or individual agent from the large companies may well be the most direct way to overcome a barrier to market or to realise value on their innovative product.

Generally then, SMEs are willing to work with other SMEs, academic groups and universities as a main source of technological inputs, either from joint projects or personal contacts with various academics. SMEs often prefer to utilise the technological inputs from PhD students who are perceived as needing little partnership infrastructure or resource, and providing a good return on financial investment. In addition to that, several SMEs recognise that working with other firms can lead to successful collaborative inventions, either with competitors or various reputable firms in the area (see appendix 1). SMEs engage themselves in collaborations at national and international levels to gain recognition, expand their presence in markets, capture potential know-how and leverage their investment portfolio. By and large such partnerships were not labelled as OI though may well have had many characteristics of OI. No collaboration was reported by a

very small number of SMEs (2), by intent, as they believe rightly or wrongly that they are the experts in the industry.

5.3 Implementation Pathways

The strategies and collaboration behaviours of SMEs all influence their adoption of OI practices. Looking into that more deeply, although most SMEs are open to collaboration in some shape or form, it does not mean that the actively do so consistently over time: we find that they are 'selectively open' in relation to financial arrangements, which may vary a great deal over the lifetime of a firm (Figure 5)

Insert Figure 5 about here

The study revealed that more than a quarter (8 out of 30) of SMEs engaged in long-term collaborative OI arrangements, or Fully OI Adoption**,** such as ongoing strong ties to other SMEs and academic groups, sometimes funded by government agencies. Almost all the rest had a commercialisation focus defining their partnering strategy, which limited the extent to which IP could be shared, thus limiting OI practice. Some SMEs were heavily focused on an intermediate exit plan (6 out of 30) or a full commercialisation approach (14 out of 30) around an industrial corporate venture. By adopting an intermediate approach, the CEOs of an SME can manage mid-term exit strategies for investors as such firms are typically seeking to be acquired within a 3-5 year window. At the same time, a very small proportion of SMEs (2 out of 30), heavily dominated by VC backing, based their strategies on a high commercial settlement.

5.4 Barriers to innovation

Whatever their long and medium term strategy, most CEOs face barriers to innovation generally that are related to the day-to-day progress and process of their action strategy, such as: time pressure; Payments/cash flow; Regulatory Hurdles; Finance and Funding; Product Failure;

Operational Governance; Loss of Contracts; Commercialisation Hurdles. Figure 6 illustrates the several issues and barriers SMEs face during their innovation processes and development progress.

Insert Figure 6 about here

Most issues and problems occur during the development and the candidate phase of emerging products, as this is the most cash draining and time consuming phase. Of course such issues pertain to both open and closed strategies, yet they can be traced both internally and externally, with CEOs stressing that tight regulatory hurdles that are in principle external to both collaborators in a partnership, tend to become internalised to one partner over time. This is typically the SME, if other partners are larger, more powerful and less dependent on the relationship. Where this happens, partnering relationships become hard to manage.

5.5 IP issues

The OI concept implicitly assumes that there is a constant source of potentially useful ideas and technologies outside the boundaries of the firm and that a firm should actively insource and or outsources its intellectual property (Chesbrough, 2003a. Therefore, a firm should not keep its intellectual property closed in-house, but it should try to find ways to profit from the use of their technology by external partners through licensing agreements, joint ventures and other arrangements (Chesbrough, 2003b). However as R&D intensive SMEs in this sector tend to be created around a portfolio of IP critical towards their business approach, indeed it is for many, their only leverageable asset in relation to obtaining further funding. While firms were willing to be open in regard to, for example, clinical information and testing protocols, IP is another matter. Still, a significant number of firms (8) expressed willingness to openly and actively engage outsourcing or insourcing of their IP, though this was usually through a funded partnership.

6. Summary and discussion

In principle, the strategies the CEOs put in motion are responsible for producing and facilitating open strategies, or otherwise, in this study. In this study, the CEOs did not see themselves as 'making decisions between open and closed systems approaches', so much as making contingent and opportunistic strategic decisions with different innovation logics around collaboration, implementation and IP as Tushman *et al.,* (2012) suggest. Tushman *et al.* (2012) argue that as the pressures to be 'more open' increase, as Chiaroni *et al.,* (2011) suggest is the case for this sector, there is a need to move beyond debates that characterise management action in regard to innovation as straightforward choices between open and closed systems. They suggest that managers must embrace the notion of complex boundary options where firms pursue multiple possibilities simultaneously, requiring different innovation logics. This seems to be the case for the firms we studied that have some degree of open-ness to their strategy (see Table 1); they were flexible in regard to implementation strategies and, to a lesser extent, IP. Those CEOs who are working on narrow product lines emerging from research laboratories chasing VC funding are likely to be bound to closed IP strategies. However, the CEO is not omnipotent and has no control over the actions of big players such as large companies, financiers, or government regulators: entities in the macro environment that affect a firm's progress and its strategy, and problems in the macro environment tended to internalise to the SME. While there may be pressures from the bigger players to foster open innovation cultures in SMEs in technological domains of interest, SME CEOs in our study were rather wary of such approaches and maybe with good reason. . There are however, a number of other strategies towards OI which mitigate risk:

- Working with lead users or potential early customers under conditions of confidentiality
- Working with other SME partners under contractual agreement (sometimes under the legal protection afforded by a contract monitored by a funding body such as the NHS or the TSB)
- Outsourcing just part of the process, such as testing or clinical trials
- Working with PhD students, as this can be quite self-contained and easy to control

CEOs do have at least a degree of control at the meso level over their internal structures, their productivity (what, and how much) and the direction of their internal capabilities. This is also related to micro level issues over talented individuals who may be internal or external to the firm. This is constrained and mediated by necessary relations with macro level regulatory and sectoral factors, and contingent relations with other firms (SMEs or large firms/meso level.

We can represent the relationships in the study as below, Figure 7 maps the hierarchy of a social structure which has particular positions associated with certain roles. Here, a CEO can design strategic decisions which when implemented, through their necessary and contingent relations (internal and external factors), deliver the on-going process of the current business model, or the adoption of a different approach.

Insert Figure 7 about here

Thus, Figure 7 clarifies the relations of the SME in question with various other firms and organisations on a meso level, and finally the relation of the firms to industrial changes, either context related or firm related on a macro level. OI may be desirable to address internal inefficiencies, or to take advantage of opportunities afforded by partners, or industry change, but this has to be in mediated circumstances, circumscribed by the demands of funders and IP protection. Mediation can be through the oversight of a contractual or funding body arrangement, or through outsourcing less sensitive areas. Despite such mediating strategies, any collaboration is subject to change over time: key individuals such as PhD students or lead users move on and the cycle must begin again; products are successful, realising revenues, or not; partnerships are subject to enrichment or degradation. Although strategic decisions are made on at the firm level, the application of an OI collaboration has a multi-layered effect, as it re-arranges the relations of the firm with individuals both internally and externally (Vanhaverbeke and Cloodt, 2006; West *et al.*, 2006). The development of OI strategies therefore changes the structure of the industry in a cyclical manner is mapped below in Figure 8, a cyclical representation of the innovation process, distinct from linear/funnel views in common usage:

Insert Figure 8 about here

7. Conclusions and further research

The purpose of this study was to examine the strategic decisions made by CEOs of UK R&D intensive SMEs in relation to OI strategies, as productivity pressures in the sector continue and increase. We focussed on CEOs or senior management team members as in SMEs they are naturally the most influential actors in the decision whether to adopt OI strategies or not. The significance of SMEs in regard to the OI concept has been stressed by others (Bianchi *et al.,* 2011; Huizingh, 2011; Keupp and Gassmann, 2009; Lee *et al.,* 2010; Lichtenthaler and Ernst, 2009; Rahman and Ramos, 2010). In this study we added to this literature, specifically for firms in R&D intensive sectors. We found that under specific circumstances and situations, SMEs in this sector use a variety of strategies during the progress of their innovation processes. Almost all the firms we studied were receptive to OI practices in some form, though there were significant variations in strategic approaches, collaboration behaviour, implementation pathways and IP issues. Thus, we extend the work of Dahlander and Gann (2010) who call for future work on the elaboration of OI, and Huizingh (2011), where the need for less descriptive and more context-aware studies is identified; further, we heed Van de Vrande's call for capturing in greater depth in the challenges of open innovation in SMEs and Attridge's (2007) call for deeper understanding of the biopharmaceutical sector, given its ongoing productivity crisis (Light and Lexchin, 2012 ; Khanna, 2012; Paul *et al.,* 2010). In doing so, we provide detailed empirical evidence as to how OI takes place in SMEs, thus addressing Dabrowska *et al.*'s (2013) concerns that there is a lack of conceptual clarity in the field which can be confusing for practitioners. We have set out in detail the range of activities that may be of potential use and mapped them to the manager's role in Figure 7. This is linked to the cyclical nature of the industry over time in Figure 8, and echo Tushman *et al.* (2012) who suggest that further research needs to be carried out to determine how the macro level shapes and is shaped by OI.

In terms of practical implications, the focus needs to be shifted from whether CEOs are labelling practices as OI, or not, to a recognition that they need to manage different innovation logics simultaneously, where different degrees of open-ness apply. While Tushman *et al.* (2012) include some very open customer/community led innovations in their discussion, we find similar implications for the life sciences sector, which is comparatively closed.

The limitation of the research is that we are confined to a relatively small sample of SMEs. Looking at the industry, as we said at the outset, OI has been hailed as a means of increasing productivity in the life sciences sector overall. Future research could explore the interactions between the SMEs, and between SMEs and large companies, which would provide greater insight into that issue; the extent to which OI is a 'solution' to the problem is unknown, at least in part due to the multifaceted nature of the sector. In building a schema of SMEs/OI that incorporates different levels of analysis and a wide range of other actors, and the relationships between them, we pave the way for theorising using meta-level approaches such as critical realism, institutionalisation or structure/agency.

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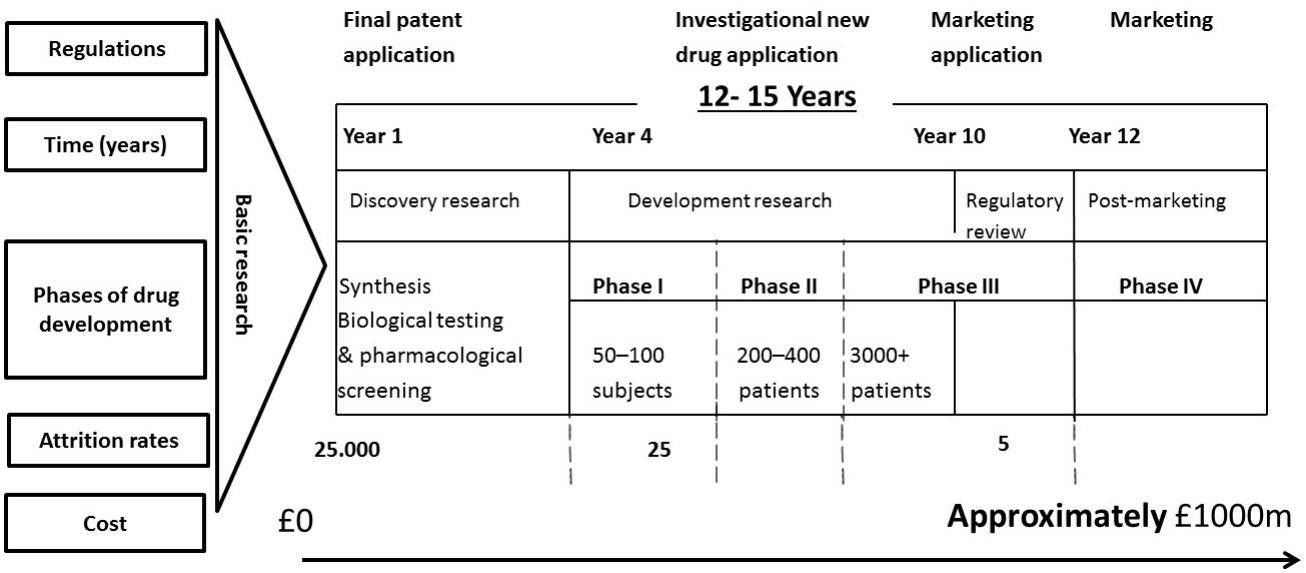
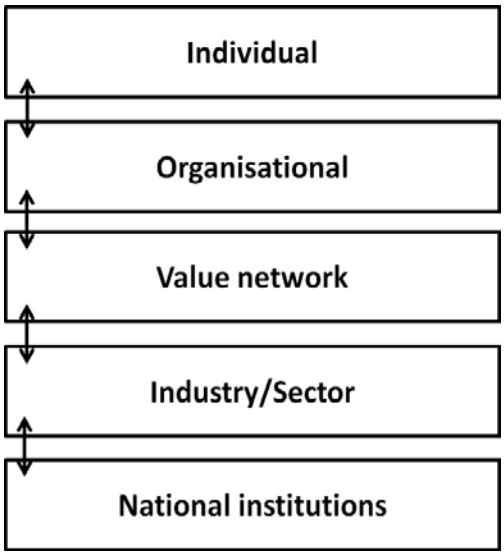
Figures

Figure 1: The Research and Development Process



Source: ABPI 2011

Figure 2: Levels of analysis in Open Innovation



Source: Chesbrough *et al.*, (2006, p: 287)

Figure 3: Multilevel approach

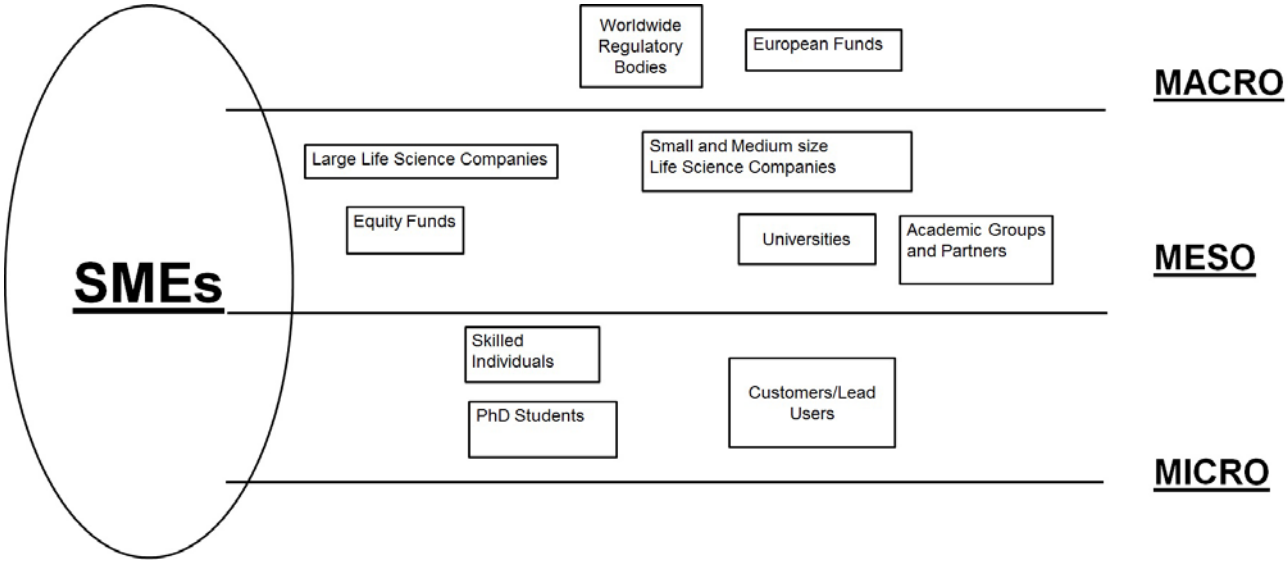


Figure 4: Collaboration Behaviour

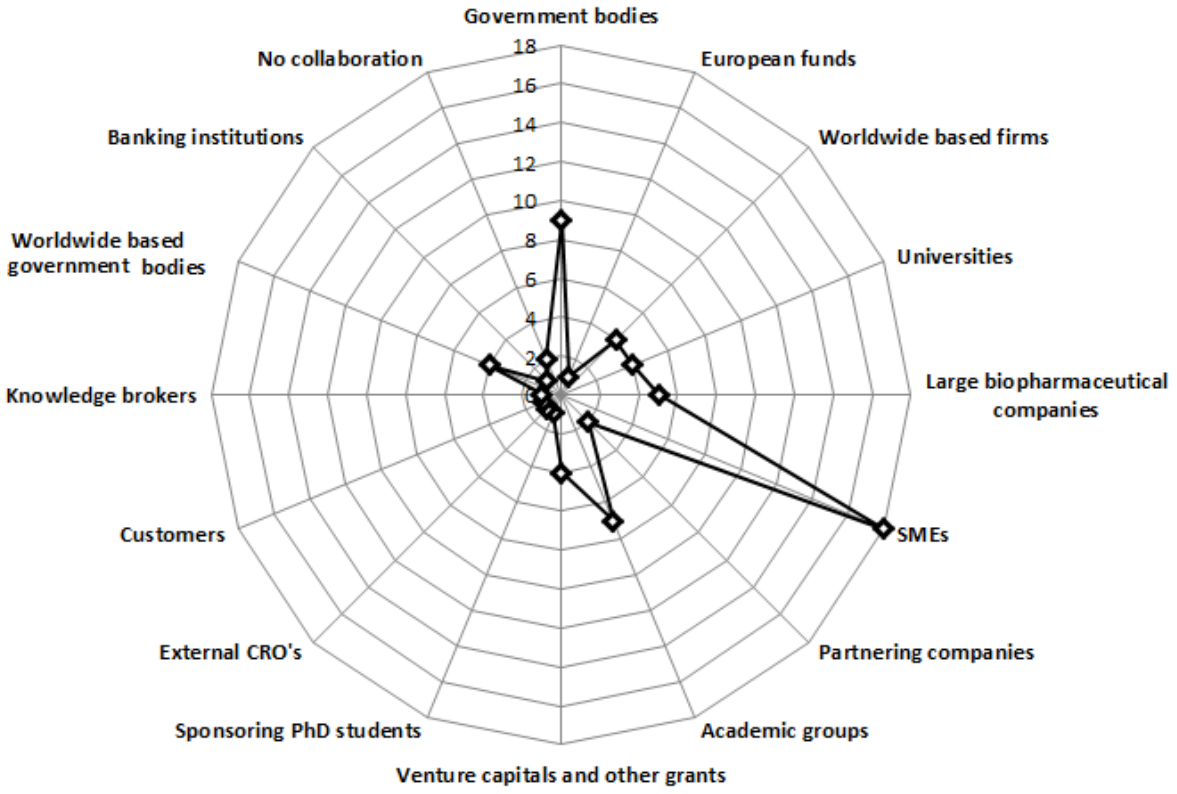
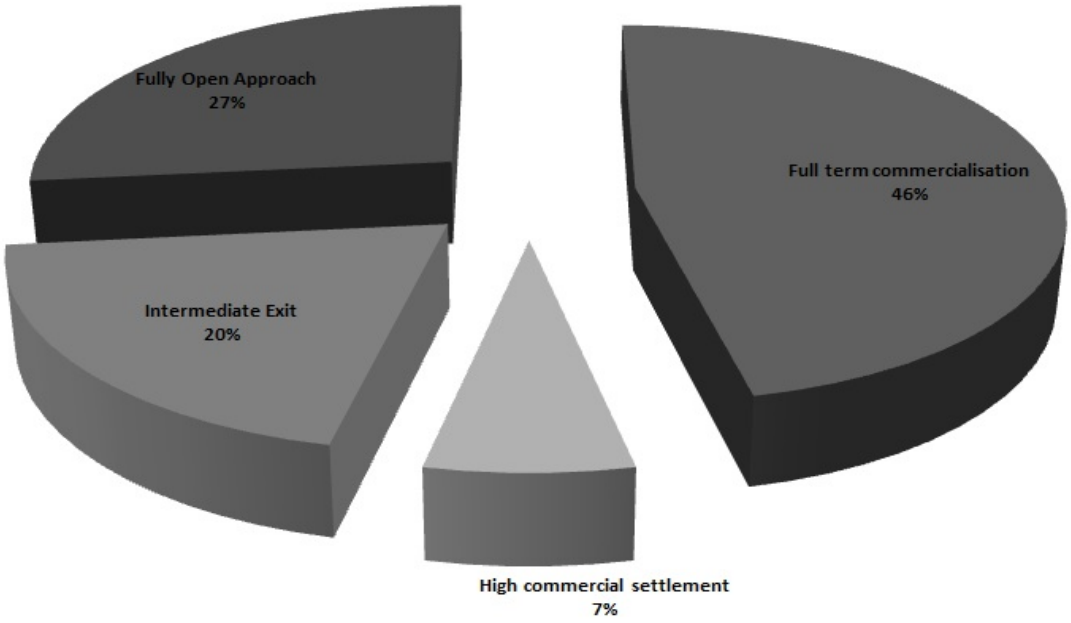


Figure 5: Implementation Approaches



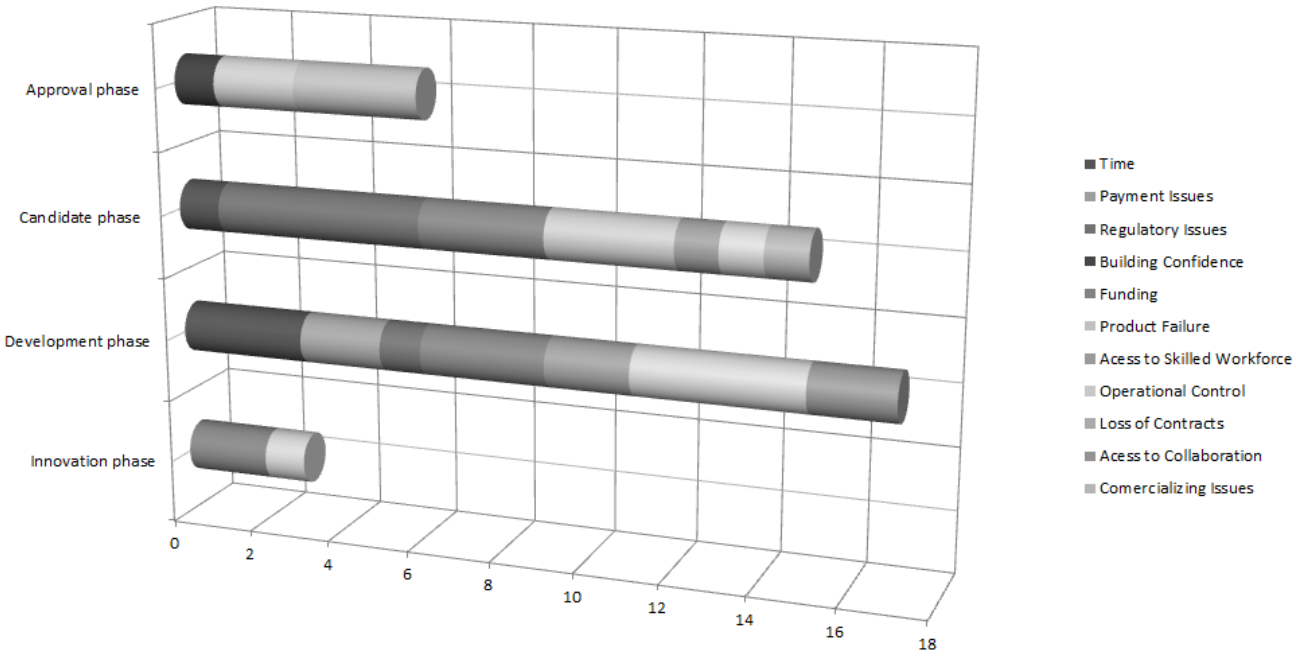


Figure 6: Barriers or Setbacks during the Innovation Process

Figure 7: OI in SMEs: relationships

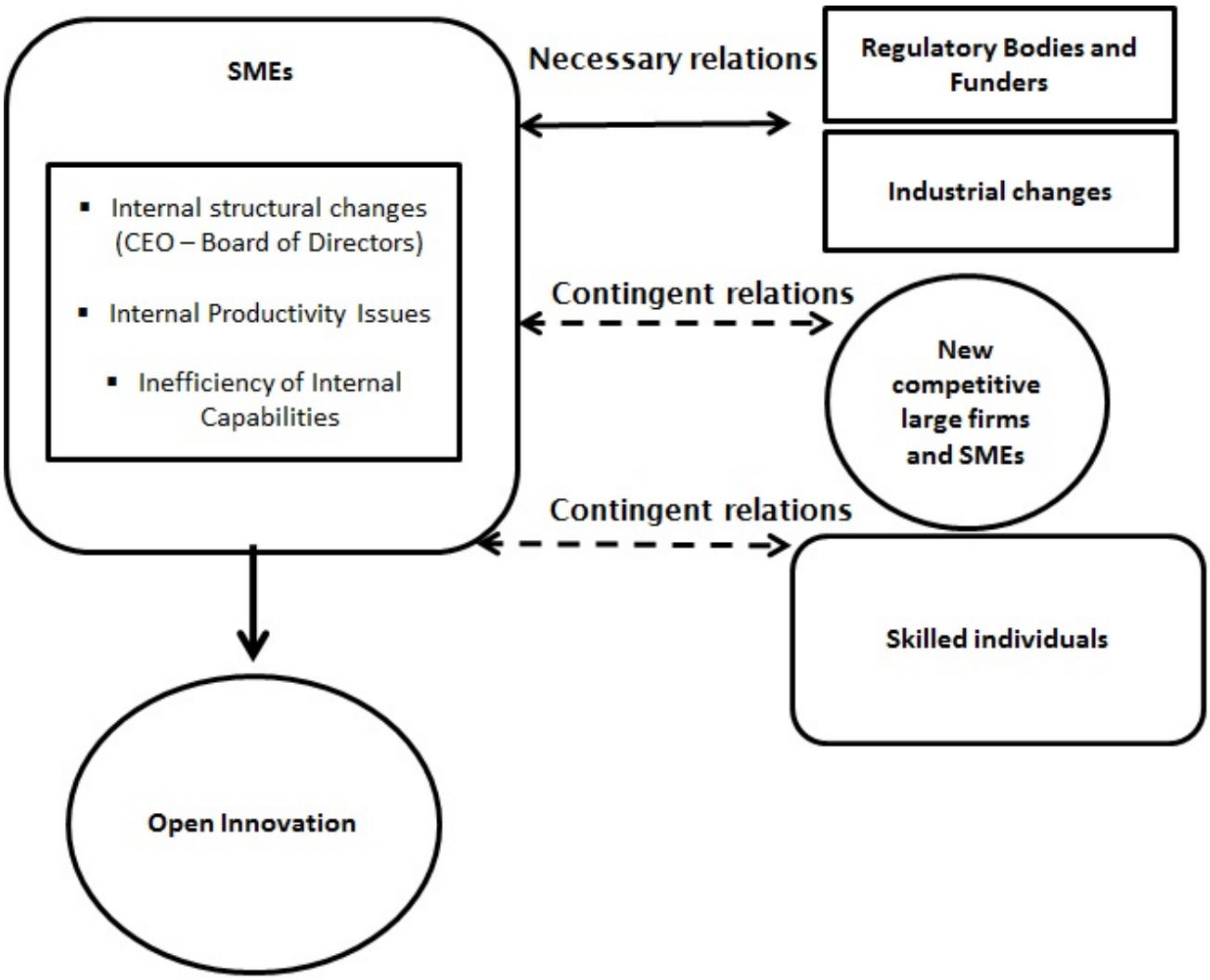
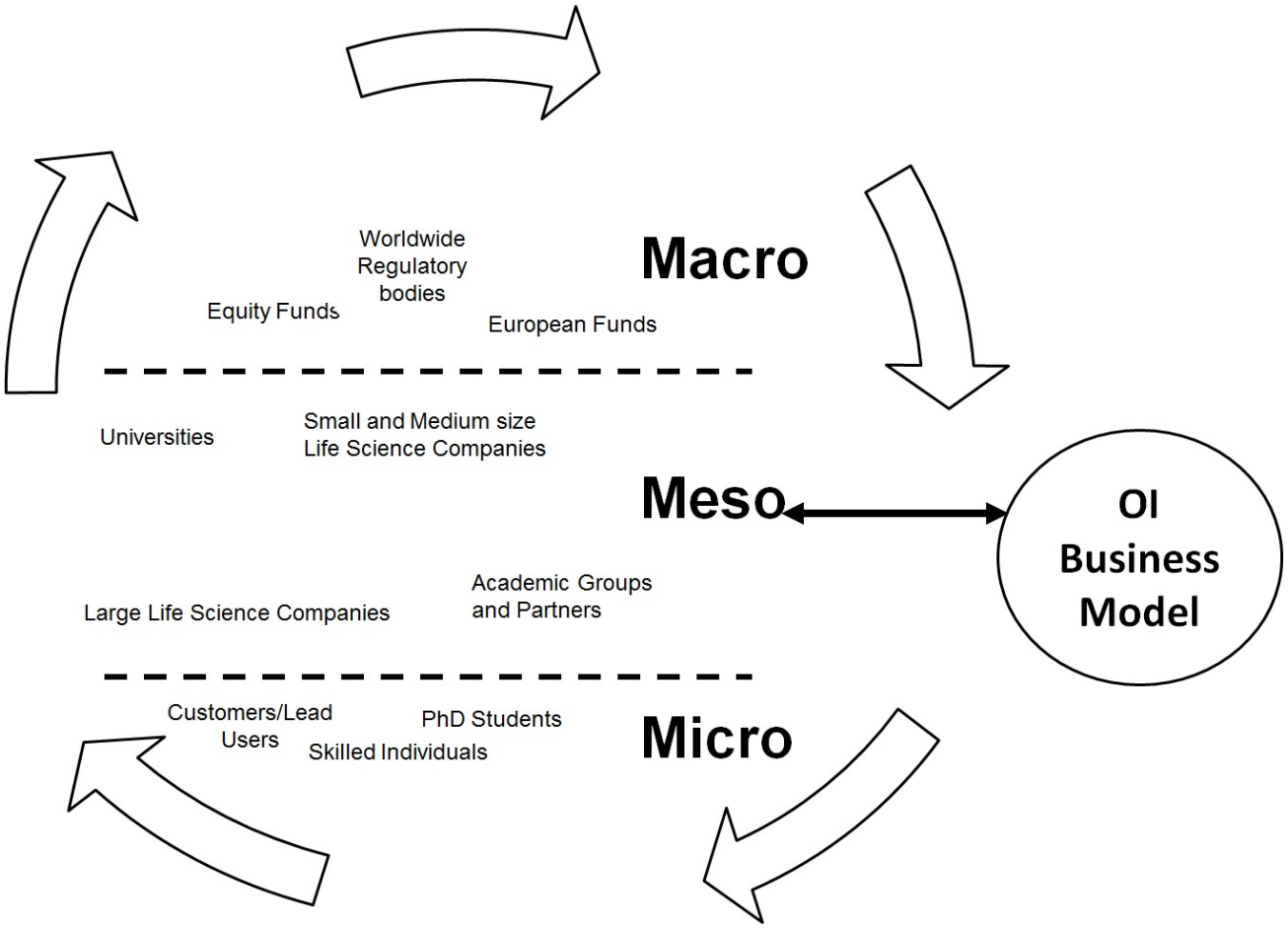


Figure 8: Cyclical nature of OI in High Tech SMEs



Appendix 1 Nvivo word/phrase table, collaboration behaviour

Approach	Actions
Co-operative Elements	Elements of open innovation but not as a strategy
	Improving in-house processes with outside help and collaborating with industrial partners
	Small team that rely on collaborations
	On subcontractor with control of the process
	Necessity to partner with other companies
	Open to joint ventures and willingness to collaborate in the same technologies
	Building a network around the firm
	Strong network of collaborations
	Interaction between companies rather than co-development of any way
Open Innovation	The freeze drying community is quite open to innovation
	Open Innovation is quite helpful, but it is not a strategy
	Noncore assets are put in open innovation
	It extends internal knowledge as well as versatility in the field
	Practicing open innovation activities
	All the pharma companies are focusing on open innovation
	Open innovation model for in-licensing and out-licensing
	Open innovation works by saying what we do not want
	Open innovation with the development of an approach to expansion
	License in deals
Non-Open	A small company with big competitors can't be totally open in terms of innovation as you cannot protect it
	Cannot acquire real value in terms of revenue as it takes open innovation time
	Not sure if it is open the way to do
	By not protecting the technology through market power, you can't be open in terms of innovation
	Very difficult to extract value from it