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**UNIVERSITY OF SOUTHAMPTON**

**FACULTY OF BUSINESS AND LAW**

School of Management

**Open Innovation in the UK Biopharmaceutical Industry: A multi-  
layered Investigation**

by

**Stefanos Marangos**

Thesis for the degree of Doctor of Philosophy

June 2014



UNIVERSITY OF SOUTHAMPTON

## **ABSTRACT**

FACULTY OF BUSINESS AND LAW

Thesis for the degree of Doctor of Philosophy

### **OPEN INNOVATION IN THE UK BIOPHARMACEUTICAL INDUSTRY: A MULTI-LAYERED INVESTIGATION**

Stefanos Marangos

Whilst the interest in open innovation is growing, thus far few studies have emphasised its importance beyond hi-tech industries and large multinationals. This research aims to generate an understanding of open innovation adoption within the UK Bio-pharmaceutical industry, which is chosen because of the significant growth it has experienced in recent times, and its heavy reliance on R&D. The findings of this multi-level study present a holistic view of the opportunities and barriers pertaining to open innovation in Biopharmaceutical SMEs and large firms, as well as indicating that open innovation strategies assist firms' in terms of value creation and capture. The study also illustrates that strategies cannot necessarily be regarded as explicitly open or closed innovation, as there is a significant spectrum of approaches in the space between.

The study's theoretical contribution develops the use of critical realism, a scientific reality which is not only about constant combinations of observable events but is also about individuals, entities and structures that exist and generate the events we witness and observe. In doing so, the study utilises an alternative to inductive or deductive reasoning, the retroductive reasoning. Through retroduction, the study explains these causal powers, mechanisms, as well as the contingent relations of individuals that are responsible for the creation of a firm's strategic considerations based on a multi-layered approach (micro-with individuals/meso-with various organisations/macro-with various government bodies and organisations).

The study comprises three sets of results, focusing on CEOs, knowledge brokers and senior executives respectively. The first set of results, based on 30 interviews of CEOs in Small-to-Medium sized Enterprises (SMEs), suggests that

open innovation practices are utilised in a multi-level, but that not all SMEs adopt the open concept. This shows the reluctance of CEOs in SMEs in sharing internal information and intellectual property. The second set, obtained from interviews with 8 Knowledge Brokers in the industry, emphasised the need for an agenda when open practices are utilised and there are personal preconceptions regarding business, which are in many cases difficult to change or adjust during open approaches. The third set, obtained from a survey questionnaire with 12 executives of 10 large biopharmaceutical firms, illustrates the importance their firms place on open innovation practices, particularly in collaborating with various firms and organisations.

In spite of the industry's recent efforts, the study identifies that benefits from the adoption of open innovation are yet to be seen, as the realisation of research and development outcomes within the Biopharmaceutical sector is a long process. Furthermore, the study clarifies that open innovation is not a monopoly of large firms in the high-tech sector, but can be adopted in various other firms in different industries. Additionally, this study contributes to the expansion of multi-layered approaches, as they give a thorough view of the processes that are involved during open innovation adoption. Finally, the research addresses the lack of empirical work in open innovation and suggests methods that identify how and why particular processes are utilised when open strategies are adopted, and elucidates the space between closed and open innovation.

# Contents

<b>ABSTRACT</b> .....	<b>i</b>
<b>Contents</b> .....	<b>iii</b>
<b>List of tables</b> .....	<b>vii</b>
<b>List of figures</b> .....	<b>viii</b>
<b>DECLARATION OF AUTHORSHIP</b> .....	<b>x</b>
<b>Acknowledgements</b> .....	<b>xii</b>
<b>1. Introduction</b> .....	<b>1</b>
1.1 The conception of open innovation.....	1
1.1.1 Relation of Closed Innovation to Open Innovation .....	2
1.2 Gap in the Literature.....	4
1.3 Research Objectives.....	5
1.4 Research Methodology.....	7
1.4.1 Biopharmaceutical Sector Focus.....	8
1.5 Contribution of the study .....	10
1.6 Structure of the thesis .....	11
<b>2. Literature review</b> .....	<b>13</b>
2.1 Innovation Discipline and Review of Innovation Theories .....	13
2.1.1 Theoretical approaches to innovation theory.....	14
2.1.2 Evolution of innovation processes .....	15
2.1.3 Multi-layered studies in Innovation .....	20
2.2 The Open Innovation Concept.....	23
2.2.1 Open Innovation Business Models .....	25
2.2.2 Reception of the open concept .....	27
2.2.3 Methodological approaches in Open Innovation.....	28
2.2.4 Examples of Open Innovation adoption .....	29
2.3 Boundaries and Barriers .....	35
2.4 Open Innovation in the Biopharmaceutical Industry.....	39
2.4.1 Innovation in the Biopharmaceutical Industry: Role of Biotech and Pharmaceutical companies .....	41
2.4.2 Knowledge Brokers in the Biopharmaceutical Industry .....	46
2.4.3 The role of SME's in Innovation .....	48
2.5 Conceptual framework.....	55
2.6 Key observations .....	62

2.7	Research Objectives and Questions .....	64
<b>3.</b>	<b>Paradigmatic underpinnings .....</b>	<b>69</b>
3.1	Introduction.....	69
3.2	Research Paradigms .....	69
3.3	Paradigms in social science.....	71
3.3.1	Positivism and Constructionism as social paradigms.....	72
3.4	Studies in open innovation.....	75
3.5	Critical realism as a paradigm of choice .....	77
3.5.1	Critical realism application in the Biopharmaceutical Sector .....	82
3.5.2	Retroductive explanations .....	85
3.5.3	Elements of analysis using critical realism .....	87
3.5.4	Explanatory view of the research process.....	89
3.6	Conclusion.....	91
<b>4.</b>	<b>Methodology .....</b>	<b>93</b>
4.1	Introduction.....	93
4.2	Methodological grounds .....	93
4.2.1	Triangulation of methods .....	95
4.3	Development of Methods .....	96
4.4	Qualitative research design and methods .....	97
4.4.1	Interviews .....	100
4.4.2	Survey Data .....	103
4.5	Data collection approach.....	105
4.5.1	Application of data collection for the study.....	106
4.5.2	Multi-layered approach “Micro – Meso – Macro”.....	110
4.6	Choosing the Outline .....	111
4.7	Conclusion.....	112
<b>5.</b>	<b>Analysis .....</b>	<b>113</b>
<b>6.</b>	<b>Open innovation in SMEs .....</b>	<b>117</b>
6.1	Innovation as a strategy in SMEs: .....	120
6.1.1	Multi-layered Analysis: Innovation in SMEs .....	123
6.1.2	Boundaries or Setbacks of Innovation .....	127
6.1.3	Multi-layered Analysis: Boundaries .....	131
6.2	SMEs: Strategic Approach.....	136
6.2.1	Multi-layered Analysis: Strategy in SMEs.....	137
6.3	In-source Approach in SMEs .....	139
6.3.1	Multi-layered Analysis: In-sourcing in SMEs .....	140

6.4	Collaborations and Networking in SMEs .....	141
6.4.1	Multi-layered Analysis: Networks and Collaborations .....	143
6.5	Evaluation of Networks in SMEs .....	149
6.5.1	Multi-layered Analysis: Evaluation of Networks .....	149
6.6	Out-source Approach in SMEs .....	153
6.6.1	Multi-layered Analysis: Out-sourcing in SMEs .....	154
6.7	Research and Development Capabilities.....	157
6.7.1	Multi-layered Analysis: Research and Development in SMEs .....	157
6.8	Intellectual Property approach .....	159
6.8.1	Multi-layered Analysis: Intellectual Property in SMEs .....	160
6.8.2	IP Management.....	162
6.8.3	Multi-layered Analysis: Intellectual Property Management in SMEs 162	
6.8.4	Change in IP Management .....	163
6.8.5	Multi-layered Analysis: Intellectual Property Portfolio Management in SMEs 164	
6.9	Engagement of Agents and Brokers with SMEs .....	165
6.9.1	Multi-layered Analysis: Agents and Brokers in SMEs .....	166
6.9.2	Multi-layered Analysis of the Impact of Brokers in SMEs .....	169
6.10	Conclusion of SMEs .....	171
<b>7.</b>	<b>Position and the Role of Knowledge Brokers in Open innovation</b> <b>173</b>	
7.1	Brokers' Perceptions of the Significance of Open innovation for the Biopharmaceutical industry .....	176
7.1.1	Attitudes during Open R&D Practices.....	180
7.1.2	Benefits of engagement with open innovation processes .....	185
7.2	Brokers' knowledge and involvement with open innovation.....	189
7.3	The role of intellectual property under open innovation.....	191
7.3.1	Involvement of Brokers and Agents with Intellectual Property under open projects .....	195
7.4	The role of Biopharmaceutical associations in Open strategies.....	199
7.5	Barriers and setbacks during open strategies.....	205
7.5.1	Attitude of participants during Open Strategies .....	212
7.6	Prospect of the open innovation approach .....	218
7.7	Conclusions on the Knowledge Broker Perspective.....	219
<b>8.</b>	<b>Open innovation in Large Biopharmaceuticals.....</b>	<b>223</b>
8.1	Studying open innovation in large Biopharmaceuticals .....	225
8.1.1	Components of the innovation process .....	226

8.1.2	Open innovation Approach across Big Biopharmaceuticals .....	233
8.1.3	Conclusions on the Large Biopharmaceutical Company Perspective 242	
<b>9.</b>	<b>Conclusions, Contributions and Recommendations .....</b>	<b>244</b>
9.1	Summary of the research outcomes .....	245
9.2	Theoretical contribution of the study .....	247
9.2.1	Critical Realism and Multi-layered factors influencing open innovation .....	248
9.2.1.1	Structure of SMEs during the implementation of their strategy 250	
9.2.1.2	Structure of Knowledge Brokers in the open innovation sphere 251	
9.2.1.3	Structure of Large Biopharmaceutical firms during the implementation of their strategy .....	253
9.3	Contribution and Concluding remarks.....	264
9.3.1	Implications for Policy .....	268
9.3.1.1	Limitations of the Study .....	270
9.3.1.2	Further and Future Research.....	271
<b>Appendices</b>	<b>.....</b>	<b>274</b>
Appendix 1	.....	275
Appendix 2	.....	277
Appendix 3	.....	280
<b>List of References</b>	<b>.....</b>	<b>292</b>

# List of tables

TABLE 1: SCHOOLS OF ECONOMIC THOUGHT .....	14
TABLE 2: LEVEL OF ANALYSIS OF THE DIMENSIONS OF INNOVATION AND OPEN INNOVATION .....	22
TABLE 3: OPEN AND CLOSED INNOVATION CHARACTERISTICS .....	24
TABLE 4: OPEN INNOVATION PROPOSITIONS .....	27
TABLE 5: FIRMS EMBRACING OPEN INNOVATION .....	29
TABLE 6: STUDIES ON SMES.....	49
TABLE 7: STUDIES OF OPEN INNOVATION IN SMES.....	51
TABLE 8: ELABORATION OF THE MULTI-LEVELS APPROACH .....	62
TABLE 9: OPEN INNOVATION IN THE BIOTECH AND PHARMACEUTICAL INDUSTRY.....	65
TABLE 10: IMPLICATIONS OF POSITIVISM AND SOCIAL CONSTRUCTIONISM.....	74
TABLE 11: NATURE OF STUDIES IN OPEN INNOVATION .....	75
TABLE 12: SCIENTIFIC PARADIGMS .....	77
TABLE 13: POSITIVISM, CRITICAL REALISM AND CONSTRUCTIVISM APPROACH .....	78
TABLE 14: EXAMPLES OF CRITICAL REALISM IN EMPIRICAL RESEARCH .....	89
TABLE 15: METHODS WITHIN REALIST METHODOLOGICAL FRAMEWORKS .....	94
TABLE 16: DATA GATHERING APPROACH .....	106
TABLE 17: DATA COLLECTION STRATEGY .....	107
TABLE 18: RESEARCH OBJECTIVES.....	114
TABLE 19: POSITION OF SMES IN THE BIOPHARMACEUTICAL INDUSTRY.....	118
TABLE 20: SCOPE AND CHARACTERISTICS OF INNOVATION STRATEGIES IN SMES .....	122
TABLE 21: BOUNDARIES OR SETBACKS OF SMES DURING THE INNOVATION PROCESS.....	130
TABLE 22: RESEARCH OBJECTIVES AND QUESTIONS.....	256

# List of figures

FIGURE 1: TECHNOLOGY PUSH (FIRST GENERATION).....	16
FIGURE 2: MARKET PULL (SECOND GENERATION) .....	16
FIGURE 3: THE COUPLING MODEL OF INNOVATION (THIRD GENERATION).....	17
FIGURE 4: INTEGRATED INNOVATION PROCESS (FOURTH GENERATION).....	18
FIGURE 5: PRODUCT DEVELOPMENT TIME/COST RELATIONSHIPS (FIFTH GENERATION) .....	19
FIGURE 6: DISSEMINATION OF INNOVATION.....	21
FIGURE 7: CLOSED INNOVATION MODEL .....	
FIGURE 8: OPEN INNOVATION MODEL .....	
24	
FIGURE 9: CLOSED VS OPEN BUSINESS MODEL .....	26
FIGURE 10: PHASES OF MANAGEMENT FADS .....	38
FIGURE 11: OPEN INNOVATION DURING THE PHARMACEUTICAL PROCESS .....	40
FIGURE 12: PHARMACEUTICAL COMPOUND PROCESS.....	43
FIGURE 13: R&D INVESTMENT IN EUROPEAN MARKETS .....	44
FIGURE 14: UK R&D DISTRIBUTION.....	45
FIGURE 15: KNOWLEDGE BROKERS AND TYPES OF KNOWLEDGE .....	47
FIGURE 16: KNOWLEDGE BROKERING INTERACTIONS .....	48
FIGURE 17: CONCEPTUAL FRAMEWORK OF THE STUDY .....	57
FIGURE 18: LEVELS OF OPEN INNOVATION INVESTIGATION .....	58
FIGURE 19: LEVELS OF ANALYSIS OF OPEN INNOVATION .....	58
FIGURE 20: DIMENSIONS OF INNOVATION .....	59
FIGURE 21: KUHN'S VIEW OF SCIENTIFIC DEVELOPMENT .....	70
FIGURE 22: RESEARCH FRAMEWORK BASED ON EPISTEMOLOGY .....	71
FIGURE 23: RESEARCH DESIGN .....	80
FIGURE 24: INTRANSITIVE AND TRANSITIVE DOMAIN .....	81
FIGURE 25: THE BIOPHARMACEUTICAL INDUSTRY STRUCTURE .....	84
FIGURE 26: RETRODUCTIVE EXPLANATION IN CRITICAL REALISM .....	86
FIGURE 27: SOCIAL STRUCTURE OF EMPLOYER AND EMPLOYEE.....	87
FIGURE 28: THE WHEEL OF COMPETITIVE STRATEGY .....	117
FIGURE 29: CRITICAL REALIST VIEW OF STRATEGY PROCESS STRUCTURE IN SMES .....	119
FIGURE 30: INNOVATION APPROACHES IN SMES.....	122
FIGURE 31: NVIVO WORD TREE OF INNOVATION USE IN SMES .....	126
FIGURE 32: BOUNDARIES OR SETBACKS DURING THE INNOVATION PROCESS .....	129
FIGURE 33: IMPLEMENTATION OF STRATEGY IN SMES .....	137
FIGURE 34: SUSCEPTIBLE TO IN-SOURCE? .....	140
FIGURE 35: STRUCTURE OF COLLABORATIONS PROCESS IN SMES .....	142

FIGURE 36: MICRO-MESO-MACRO LEVEL OF COLLABORATIONS IN SMES.....	143
FIGURE 37: SOURCES OF FUNDS FOR PHARMACEUTICAL BUSINESS IN THE UK.....	146
FIGURE 38: NVIVO WORD TREE – COLLABORATION IN SMES.....	148
FIGURE 39: DISTRIBUTION OF COLLABORATIONS IN SMES.....	152
FIGURE 40: STRUCTURE OF R&D STRATEGY IN SMES.....	153
FIGURE 41: OUT-SOURCE STRATEGY IN SMES.....	154
FIGURE 42: INTELLECTUAL PROPERTY STRUCTURE IN SMES.....	160
FIGURE 43: SIGNIFICANCE OF INTELLECTUAL PROPERTY FOR SMES.....	161
FIGURE 44: INNOVATION PROCESS STRUCTURE ENGAGEMENT WITH BROKERS.....	166
FIGURE 45: USE OF BROKERS AND AGENTS BY SMES.....	169
FIGURE 46: THE INNOVATION MARKETPLACE OPERATOR.....	174
FIGURE 47: ENGAGEMENT OF BROKERS AND AGENTS.....	176
FIGURE 48: NVIVO WORD TREE OF OPEN INNOVATION PERCEPTION OF BROKERS.....	179
FIGURE 49: RESEARCH AND DEVELOPMENT COLLABORATIONS IN CRITICAL REALISM.....	181
FIGURE 50: STAKEHOLDER GAINS THROUGH OPEN COLLABORATIONS.....	187
FIGURE 51: IP PROCESS IN OPEN INNOVATION.....	192
FIGURE 52: IP AND THE INVOLVEMENT OF AGENTS AND BROKERS.....	196
FIGURE 53: TRADE ASSOCIATIONS IN THE BIOPHARMACEUTICAL INDUSTRY.....	200
FIGURE 54: THE OPEN INNOVATION CONTEXT PROCESS.....	206
FIGURE 55: SETBACKS, DIFFICULTIES AND BARRIERS UNDER OPEN INNOVATION PROJECTS AND PROCESSES .....	209
FIGURE 56: PHARMACEUTICAL PROCESS DURATION AND STRATEGY.....	218
FIGURE 57: CRITICAL REALIST VIEW OF STRATEGY PROCESS IN LARGE BIOPHARMACEUTICALS.....	225
FIGURE 58: SATISFACTION WITH THE CURRENT BUSINESS STRATEGY.....	227
FIGURE 59: SATISFACTION LEVELS DURING THE ASSIGNMENT OF A PROJECT.....	228
FIGURE 60: DISTRIBUTION OF COLLABORATIONS AND NETWORKS UNDER OPEN ARRANGEMENTS.....	231
FIGURE 61: VARIATION OF OPENNESS IN LARGE ORGANISATIONS.....	235
FIGURE 62: MOTIVES FOR OPEN INNOVATION ENGAGEMENT.....	236
FIGURE 63: NETWORKS SPATIALITY OF LARGE BIOPHARMACEUTICALS.....	239
FIGURE 64: BARRIERS AND SETBACKS DURING OPEN PROJECTS.....	240
FIGURE 65: THE STRUCTURE OF CAUSAL EXPLANATION IN CRITICAL REALISM.....	249
FIGURE 66: FACTORS INFLUENCING OPEN INNOVATION IN SMES.....	250
FIGURE 67: FACTORS INFLUENCING THE PRESENCE OF KNOWLEDGE BROKERS IN OPEN INNOVATION.....	252
FIGURE 68: FACTORS INFLUENCING OPEN INNOVATION IN LARGE FIRMS AND ORGANISATIONS.....	254

# DECLARATION OF AUTHORSHIP

I, Stefanos Marangos declare that the thesis entitled “Open Innovation in the UK Biopharmaceutical Industry: A multi-layered Investigation” and the works presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
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- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- parts of this work have been published before submission as follows:

Marangos, S. Warren, L. Thomas, S. R. (2013), Open Innovation in the Biopharmaceutical industry: Does size matter? Institute for Small Business and Entrepreneurship (ISBE) conference 2013 Cardiff: November 2013

Marangos, S. Warren, L. Thomas, S. R. (2013), Is Pharma open for innovation? UIST Health and Pharma One Day Conference - Bench to Clinic: Partnership with Health and Pharma, Southampton: June 2013 - Poster presentation

Marangos, S. Warren, L. Thomas, S. R. (2012), Open Innovation: Opportunities and Barriers in the UK Biopharmaceutical industry, International Conference in Socially Responsible and Sustainable Entrepreneurship and Innovation - Southampton: October 2012

Marangos, S. Warren, L. Thomas, S. R. (2011), Open Innovation: Opportunities and Barriers, International Conference in Entrepreneurship, Innovation and SMEs - Caen - FRANCE: November 2011

Marangos, S. Kitagawa, F. and Warren, L. (2010), Networks and Spatiality of University Incubators: Global and local links amongst SETsquared Spin-off/-in firms at Universities of Bath, Bristol, Southampton and Surrey in England, 2010-R03. San Sebastián, Spain: Basque Institute of Competitiveness (Orkestra) (JEL Classification: L, O, R).

Singed: .....

Date:.....

# Acknowledgements

I wish to express my sincere gratitude to my supervisors Dr Lorraine Warren and Dr Stephen Rhys Thomas for their guidance, support and most of all their patience through the long journey of my PhD. Additionally, special thanks to Karl Simpson, Head of Life Sciences (Health & Pharma sector lead) of the University of Southampton and Gavin Clark, Managing Director of Marlin Bioconsulting Limited for their supportive guidance during the interview process.

I would like to thank my wife Jing Hu, who is always next to me, cheering me up and standing by me through good times and bad, as without her love and support I would not be able to carry on. Moreover, I would like to express my gratitude to my parents Giannakis and Chryso for their love, support and encouragement over the years.

I wish to thank Christina Soteriou for her guidance during the early years and Thasos Michaelides, President of the Cyprus State Scholarship Foundation for his support through the financially difficult times. Moreover, I would like to thank Nicholas Zonias and Edward John Boscaro for being there through the difficult times, and my colleagues from the 3<sup>rd</sup> floor of the School of Management for the great time we had through the duration of my study.

Finally, I extend my thanks to the participating companies as without their help this study would not be possible.

# 1. Introduction

## 1.1 The conception of open innovation

Open innovation, a concept introduced by Chesbrough (2003a), stresses that ideas that come either from inside or outside a company can go to the market, and that companies that base their business models on identifying and exploiting external ideas have the opportunity to reveal their financial gains (Chesbrough and Garman, 2009).

In an environment of strong competition and shortage of resources, firms and organisations are constantly on the lookout for new and improved approaches that can maximise value, and reduce their costs. Traditionally, the use of closed innovation strategies has implied that the processes of developing new products are solely undertaken by the firm's internal R&D department (Chesbrough, 2003a). As a new application within the management of a firm, it is claimed that open innovation is set to force firms to reassess their leadership positions, which reflect the performance outcomes of their business models and strategies (Chesbrough and Appleyard, 2007).

The implementation of open innovation requires the innovating firm to use a number of managerial levers, by which the change process unravels four key levers where the implementation of open innovation has an impact have been identified (Chiaroni et al, 2009):

- Networks -Establish relationships between the firm and a variety of partners: universities and research institutions (Perkmann and Walsh, 2007), suppliers (Emden et al, 2006), and users (von Hippel, 2005; Simard and West, 2006; West and Lakhani, 2008).
- Organisational structures - Engaging externally acquired knowledge requires the development of complementary internal networks (Hansen and Nohria, 2004).
- Evaluation processes - Procedures to systematically scan and monitor the range of technologies in the external environment (Van de Vrande et al, 2006), as well as new forms of external sources of innovation

through the strategic use of corporate venturing (Keil, 2002), appear to have an increasing importance for outside-in open innovation.

- Knowledge management systems - Adopting knowledge management systems will foster the diffusion, sharing and transfer of knowledge within, between, and with, the external environment of the firm (Wang, and Noe, 2010).

As an increasing number of big corporations adopt the concept of open innovation, it is becoming more of a strategy rather than a buzzword, as reflected by the growth in the literature on the subject (Van der Meer, 2007, p. 201). In addition to this, since its introduction, several studies have shown the successful adoption of open innovation within the management discipline, most noticeably Gassmann and Enkel (2004), Gassman (2006), Spithoven et al (2010), Chiaroni et al (2011) and Lichtenthaler (2011).

### **1.1.1 Relation of Closed Innovation to Open Innovation**

None the less, nowadays, studies of innovation have pointed out the growing relevance of external sources of innovation, rather than the company relying on internal R&D (Perkmann and Walsh, 2007). Organisations are reported to be increasingly engaging in open innovation (Chesbrough 2006), with studies suggesting that innovation can be regarded as the result of distributed inter-organisational networks, rather than resulting from single firms and linear innovation processes (Coombs et al. 2003; Perkmann and Walsh, 2007; Powell et al. 1996).

In contrast with the closed innovation model, open innovation is argued as progressively providing for a more diffused, and more externally focused way of organizing innovation (Chesbrough, 2003a). Although large companies, such as Xerox, IBM and Intel, have adopted open innovation strategies, which appear to be convincing, as the technological and financial gains appear to have had a global impact (OECD, 2008), Gassman et al, (2010) have argued that most companies in an economy are SMEs, and that they are under-researched in the open innovation literature.

In relation to current models of innovation (Rothwell, 1994), it has been suggested that the open innovation model has two dimensions, the inbound and the outbound (Chesbrough, 2003a). Inbound open innovation refers to leveraging the research and development of external agents and acquiring external knowledge resources from a network in order to develop new products. In contrast, outbound open innovation refers to the commercialisation of internal research and development outputs to external organisations (i.e. licensing, joint ventures, spin-offs). As a result, open innovation offers managers who work in established asset-intensive industries, a great number of insights that can stimulate their own observations regarding the organisation, the process of implementation of open innovation, and how to improve the chances that it will be completed successfully (Chiaroni et al. 2009, p. 301).

In recent times, several firms across a variety of industries have been reported to be adopting open approaches, with large biopharmaceutical companies, such as GSK, Pfizer and Elly Lilly, claiming to be among the pioneers of its implementation (Hunter and Stephens, 2010). Indeed, the adoption of open innovation has been identified as one of the main trends in pharmaceutical innovation (Fredberg et al, 2008), where developing collaborations with the right partners is seen as an important factor for success, as the costs of in-house development continue to rise (Gassmann and Reepmeyer, 2005). Biopharmaceutical companies recognise the significance open innovation may have in R&D management, and are actively diversifying their projects towards the open innovation paradigm (ibid). Pharmaceutical and Biotech companies have successfully adopted open innovation practices (Chesbrough 2003a, 2003b, 2003c, 2003d), with evidence showing the positive attitude in open innovation to be strong in particular industries (Laursen and Salter, 2005).

As it has been claimed to actively allow ideas that come from either inside or outside the company to go to the market (Chesbrough, 2003a), it becomes vital to confirm whether open innovation processes assist in value creation or capture. It is imperative to identify how open innovation contributes to value creation, in terms of technological and financial gains for companies in the Biopharmaceutical industry. Acknowledging that open innovation is a direct business approach, it is important to evaluate how, and why, companies adopt

open practices, and whether networks of innovation with other organisations have been established, in terms of creation of opportunities and the raising of barriers during such strategic applications. Nonetheless, some criticism has been raised suggesting that the open innovation concept has emerged without much critical analysis or definition, indicating that its elements are evident in earlier conceptions of innovation (Mowery, 2009, Trott and Hartmann, 2009).

## 1.2 Gap in the Literature

A review of the literature in chapter 2 reveals several gaps in knowledge concerning open innovation in the Biopharmaceutical industry. This study, therefore, proposes a multi-layered investigation to identify the opportunities and barriers that such approaches offer to individual firms, and the industry as a whole:

1. To date, most studies that investigated open innovation have been of a descriptive nature, and do not answer the questions about why, how and when open innovation practices occurred. Consequently, this study addresses these issues by introducing an explanatory view on the investigation of open innovation practices. By doing so, the causal mechanisms, contingent relations and emergent powers of the individuals who are responsible for the emergence of such strategies will be identified. There is a distinctive lack of empirical work on a multi-level in the contexts of the individual, sectorial and governance levels (micro-meso-macro). These missing elements include the role of individuals, the processes of exchange of information and ideas, and the interactions with governing bodies, which will deliver a better understanding of the results.
2. The attention of research in open innovation is mainly focused around large, high-tech and international enterprises, with few studies demonstrating its existence in other sectors and segments of the economy.
3. Sectors such as the Biopharmaceutical industry and the firms and organisations that populate it have not received extensive research or much attention from studies in open innovation, it is important to grasp

the opportunity to explore the open innovation concept within this context.

4. Given that the majority of studies in open innovation have not included SMEs, the present study grasps the opportunity to explore the opportunities and barriers open innovation offers to SMEs in this context. As SMEs represent the vast majority of employers and claim to enhance competition and entrepreneurship, this focus is critical for a deeper understanding of the dynamic functioning of the Biopharmaceutical sector as a whole.
5. As nowadays Biopharmaceutical firms find it difficult to carry on with their internal R&D, knowledge brokers and agents can play an important role as intermediates by influencing and facilitating several collaborative projects. This is an indication that knowledge brokers can be used as an important source of information concerning the directions and attitude of not only the firms but the sector as a whole.

Several studies have indicated the importance of open innovation in developing better and novel technologies and services (Chesbrough 2003a, 2003b, 2003c, 2003d; Chesbrough et al, 2006; Chesbrough and Crowther, 2006; Laursen and Salter, 2005). Nonetheless, most studies are of a descriptive nature and narrow their focus to multinational companies rather than the whole spectrum of industries and sectors. Moreover, the attention of current studies is narrow in terms of its methodological grounds; an alternative focus such as critical realist epistemological perception (Bhaskar, 1978), which encourages retroductive reasoning can deliver a more robust and analytically powerful conceptualisation of context which is displayed in most of the published co-evolutionary studies (Clark and Blundel, 2007, p. 48).

### **1.3 Research Objectives**

Even though there is widespread adoption of the open innovation concept, particularly in large high-tech firms and multinational corporations, little is known about its adoption by small and medium size enterprises (Colombo et al, 2014; Lee et al, 2010; Spithoven et al, 2013). As large companies and corporations have engaged in open innovation activities to date only a limited

number of studies have examined open innovation adoption by SMEs (ibid). The aim of this research is to gain understanding of open innovation practices within the Biopharmaceutical sector and the opportunities and barriers it represents, in terms of value creations and capture. By capturing the perceptions of senior management in SMEs and in large corporations, as well as knowledge brokers, the research aims through the explanatory lens of critical realism to elucidate the processes, structures and causal mechanisms of open innovation in the Biopharmaceutical industry. To do this effectively, the research has three objectives:

- 1) Explore the processes and relationship of and between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies.
- 2) Demonstrate the significance of open innovation strategies in terms of its fundamental properties and features, such as in/out source, IP in/out source and open collaborations.
- 3) Explain how critical realism assist in studying and explaining the structure of open innovation processes within the Biopharmaceutical sector.

To provide an insight in the open innovation framework and to create an understanding of the opportunities and barriers the concept creates for Biopharmaceutical companies, the study provides:

- o A thorough investigation of the open innovation concept within the context of an innovative sector (Biopharmaceutical).
- o The use of a multi-layered architecture framework stresses the role of firms and their perspective, but more importantly the role of individuals within a firm, as well as sectorial elements and sectorial structure, which has so far been ignored by the research on open innovation.
- o As a critical view has not been utilised thus far (explaining events by identifying and explaining the underlying mechanisms), so the study will provide a solid understanding of how they occur when open innovation strategies are exercised.

As the study focuses on identify the entities and objects that are associated with the adoption of open innovation practices, the use of retroduction reasoning can identify the specific nature and the causal powers of entities and objects that adopt such strategies (Bhaskar, 1978).

## **1.4 Research Methodology**

As mentioned above, for the purpose of this study, a critical realism approach is adopted to understand the relationships between key players in the innovation process (Bhaskar, 1979, Sayer 1992; 2000; 2004). Since its introduction by Bhaskar (1975), critical realism has emerged as one of the most influential new directions in the philosophy of science and social science, offering a real alternative to both positivism and post modernism (Archer et al. 1998). Critical realism is appropriate for this study as it views reality as a complex and multiple rational; it recognises the significant role of agency and structural factors that influence human behaviour, which can be explained through the use of qualitative and, or quantitative research methods (Given, 2008, p. 167).

For this study, critical realism is adopted as it embodies a number of much more powerful ontological assumptions about the nature of reality, which provide a more articulated view of its characteristics (Easton, 2002, p. 105). The specific focus recognises the need to separate and prioritise ontology (“what exists?” means the limitations of human understanding because of human mental limitations) from epistemology (“how can we know what exists?”) (Noonan, 2008), as we probe the adoption and development of the open innovation concept in the biopharmaceutical industry. As the primary objective is to define the use of open innovation at the individual level, the exploration of the open innovation concept in both the actual and the “empirical domain of reality” are imperative as otherwise the explanation of the “empirical domain of reality” can be incomplete.

A critical realist aim perceives that reality is stratified and structured from the actual and empirical domain (Bhaskar, 1978). In this sequence, reality is constructed based on the actions of the actors or the objects that are empirically observed (ibid), which is similar but not the same to positivistic

approach, which defines that reality is constructed from the identification of events that occur throughout direct observations based on quantitative data collection methods (Orlikowski and Baroudi, 1991). As mentioned earlier, critical realism attempts to detect and categorise the underlying causal powers and mechanisms of reality which exist in the actual domain (Bhaskar, 1978, Sayer 1992). These causal powers and mechanisms can explain the events that have emerged through the examination of the actual and the empirical domain from data that are collected by various qualitative methods such as semi structured interviews or questionnaires (Mingers, 2000, p. 1262; Sobh and Perry, 2006).

As the research aims to use multiple data sources to trace out the relation that moves from the actual to the real domain (Sayer, 1992), it leads to the acceptance of a multi-layered ecosystem. This ecosystem validates the relations of SMEs - knowledge brokers - large companies towards the adoption of open innovation. Amongst others, the significance of a critical realist focus not only provides the researcher the structural and hierarchical importance and position of the individuals who are involved in creating or adopting a new strategy, but also the ability to utilise a mixed methods research and to choose a methodology suitable for the research (Mingers, 2000). To investigate open innovation in the Biopharmaceutical sector, a multi-layered approach based on a Micro - Meso - Marco method (Dopfer and Potts, 2004) can be employed to examine the open strategies. In doing so, the study will assess the perspective of CEOs in small-medium sized enterprises, knowledge brokers and CEOs in large companies, as well as the position of the biopharmaceutical sector towards the open approach by identifying the causal mechanisms behind such practices and strategies.

### **1.4.1 Biopharmaceutical Sector Focus**

Being among the largest industrial sectors in the UK, the Biotech and Pharmaceutical sectors have been reported to be amongst the highest revenue generator industries in the UK, with a balance of £35.200.000.000 in 2011 and the highest investment in medicine research and development in Europe (Strength and opportunity 2011). Furthermore, they are characterised by large multinational corporations and SMEs, thus the study will make an

analysis of the SMEs processes based on an interview examination with their senior management. Additionally, the study will incorporate interviews from knowledge brokers who play a significant role as intermediaries between SMEs and large firm. Finally, an online survey with the senior management of large companies as units of observation will give a detailed view of the adoption of open strategies.

The pharmaceutical industry is a good example of adventitious and complicated technology that requires a significant investment, as the cost of research, development and testing of new drugs requires large and long-term investment well before any rewards can be secured (Bainbridge, 2009, p. 369). As strategy is defined to be a set of related actions that managers take to increase their company's performance (Hill and Jones, 2010, p. 3), open innovation can be considered as a strategic model, as it assists firms in expanding their technological capabilities. A significant amount of time during the research (2011-2013) was spent on planning and collecting primary data from various sources.

To develop a deep understanding of the adoption of open innovation in the UK Biopharmaceutical industry, the study included a variety of organisations and individuals who are directly connected and related to the sector. In doing so, the researcher acquired the samples from the ABPI, who is the Association of the British Pharmaceutical Industry and the BioIndustry Association, known as BIA. The purpose was to expand the portfolio of participants across the UK and also to make sure that the selected firms and organisations are recognised and accredited within the industry. For the purpose of this study, data are collected from key actors in positions responsible for creating and facilitating innovation (CEOs, Directors and Knowledge Brokers) in two methods as follows:

### **Method 1:**

Primary: 30 Semi-structured in-depth interviews with CEOs of SMEs (Selective Sampling - Cross sectorial)

Follow up: 8 Semi-structured in-depth interviews with Knowledge Brokers (Selective Sampling - Cross sectorial)

### **Method 2:**

12 Online survey questionnaires from CEOs and Directors of large firms  
(Selective Sampling - Cross sectorial)

The data will be analysed in three stages. Stage one analyses the formation of interviews with SMEs; stage two the data from knowledge brokers; and the third stage the data from the online survey with CEOs of large Biopharmaceutical firms. The study will examine the adoption of open innovation, by creating codes from the structured interviews and the online survey. Furthermore, through the development of analysis of the interactions between SMEs, knowledge brokers and large companies, the study will present a detailed report on the current situation of the Biopharmaceutical sector in terms of the open innovation adoption by explaining why, how and when such strategies occur.

## **1.5 Contribution of the study**

As an emerging concept with actual or potential implementation in a variation of business segments on a global scale, the importance of the open innovation model currently seems to be central to both the academic as well as the political debate (Chiaroni et al. 2009). Subsequently, the study evaluates the various approaches within the UK Biopharmaceutical sector from the perspective of SMEs, large firms, and knowledge brokers.

This study makes a methodological contribution by revealing the processes, causal powers and mechanisms of the individuals that create or adopt a new strategy. These elements have not been adopted in previous studies and explore the process of open innovation. In doing so, the use of a critical realist lens perceives open innovation as an interaction between actors - individuals, through the empirical observation of events that contribute to a larger event. In principle, by categorising real entities with their causal mechanisms and powers create actual strategies which can be empirically observed and experienced (Bhaskar, 1978, p. 13). Furthermore, by adopting a critical realist approach, the research will clarify the extent of the concept of open innovation, by delivering the actual reasons why firms adopt such open strategies, as well as the opportunities and barriers such strategies carry. As the characteristics of the Biopharmaceutical industry are formulated through

social interactions of entities such as individuals, critical realism can illustrate and explain the application of the individuals' causal powers (Sayer, 1992; Mingers, 2000, Morton, 2006), to evaluate a situation or an event, such as the adoption of open innovation.

In this way, the study utilises the procedures senior managers such as CEOs (entities) formulate their decisions (causal mechanisms and powers) which lead to strategies (events) that can be empirically observed through interviews and questionnaires. The factors influencing the adoption of open innovation are the causal mechanisms and powers of objects (individuals) and entities (firms) that are consequential in the equilibrium, such as their existence at the individual, firm and contextual-industrial level. By implementing a multi-layered focus for the investigation of open innovation, the study captures the various and specific elements, as well as the processes that influence the adoption or rejection of such strategies.

This research, will create a better understanding regarding the interactions with SMEs, brokers and large firms and to the extent to which the adoption of open innovation has been significant for the creation and expansion of value. Additionally, the study will show how effective open innovation practices influence the progress of a firm and whether the decisions of the involved individuals have an effect on the progress of Biopharmaceutical process. The study will capture how SMEs relate their strategies towards adopting new and promising business models. On this, the study will demonstrate and clarify the attitude of large biopharmaceutical firms in following the leader when particular industrial strategic changes occur. In addition, it will explain how knowledge brokers as industrial experts observe the open innovation concept in the industry, and shed light whether this open approach has been proven or is becoming the dominant business logic.

### **1.6 Structure of the thesis**

The thesis consists of 9 chapters. Chapter 1 consists of an overall introduction of the study. Chapter 2 presents a systematic review of the emergence of open innovation within the management literature. In chapter 2, the gaps concerning the open innovation concept are identified and the research questions are

formulated in detail. Chapter 3 presents the paradigmatic and conceptual justifications which result in the use of critical realism as a focussing lens for the empirical research and the retroductive explanations of the data analysis. Chapter 4 presents the research methodology. Chapter 5 presents how the analysis will be constructed. Chapters 6, 7 and 8 presents the analysis of the study, including the interviews with SMEs in chapter 6, knowledge brokers interviews in chapter 7, and the survey questionnaires with the CEOs of large Biopharmaceutical firms. Chapter 9 consists of the conclusions of the study and the discussion of the results, and concludes the research with the implications of the study, its limitations and suggestions for future research.

## **2. Literature review**

This chapter provides a detailed review of the literature in innovation and the emergence of open innovation. The research identifies studies and publications on the subject of innovation from different and relevant sources, including several online websites such as Science Direct and Web of Knowledge, which were published from the early 1900s up to 2013. In doing so, keywords were used to classify information concerning the subject of open innovation including: innovation process, open innovation, external collaboration networks, pharmaceutical innovation, and Biopharmaceutical process. The study identifies the significance of different groups and schools of thought and their relation to empirical work in innovation. With a total of more than 200 key studies around the subject of open innovation, the literature review is used to frame this emerging field. As earlier studies and perspectives of innovation are positioned relative to the open innovation framework, the main purpose is to provide a proficient interpretation about the perception of open innovation in the Biopharmaceutical industry. By developing the research framework, the study identifies the gaps in terms of existing knowledge within the literature and formulates aims and objectives that will be examined.

### **2.1 Innovation Discipline and Review of Innovation Theories**

Innovation has been described by Schumpeter (1934) to be a reflection of novel outputs. Such outputs can be a new product or a new quality of a product, a new method of production, new market, and new source of supply or a new organisational structure. Similarly, various scholars labelled innovation as “new product and processes” (Tushman and Moore, 1982), or described it as “a new idea, which may be a reprocess of old ideas, a scheme that challenges the current order, a formula, or a unique approach” (Van de Ven, 1986, p. 591). Traditionally, innovation has been considered as a linear process where ideas and inventions are generated within the firm’s own research laboratories, with basic research, and ending with the development of new products (Mowery, 1983; Nelson, 1959).

This thesis is concerned primarily with research and development capabilities that have been strongly associated with innovation by a number of researchers, directors and executives within the area of technology and innovation management (Herzog, 2008). They have argued that ideas and inventions are generated within the firm's own research laboratories and any additional development into commercial products can be accomplished by the firm's own manufacturing department (ibid). The particular model known as the closed model, which is acknowledged as the hierarchical governance mechanism holds the intellectual property exclusive to the firm and the firm retains control over the development process (Sawhney and Prandelli, 2000, p. 24). The following sections highlight the concepts of innovation and their application within the management discipline, subsequently the study highlights the importance of innovation in recent times.

### 2.1.1 Theoretical approaches to innovation theory

Several schools of thought emerged in strategic management which are seen as fundamental drivers of innovation performance and competitive advantage (Conner, 1991), presented in Table 1.

**Table 1: Schools of economic thought**

Model	Theme
Neoclassical model (McNulty, 1968)	Perfect competition
Bain-type model (Bain, 1954, 1968)	Industry structure
Schumpeterian (Schumpeter, 1950; Nelson and Winter, 1982)	Competition
Chicago school (Stigler, 1968; Demsetz, 1973)	Economic thought
Transaction theory (Coase, 1937; Williamson, 1975)	Avoidance of opportunism

Source: Mahoney, 2001, p. 652

Traditionally, innovation researchers have focused on social factors and influences, such as demographic changes, economic influences, cultural changes and individual talents (Trott, 2005, p. 21). In recent years, scholars in innovation research have focused their thoughts around two main schools that determine innovation (ibid): the market-based view, which argues that market settings provide the context which facilitate or compel the extent of firms' innovation activity (Slater and Narver, 1994; Porter, 1980, 1985), and the

resource-based view, which considers that a market-driven direction does not necessarily provide a secure foundation for formulating innovation strategies for markets, which are dynamic and volatile, but rather a firm's own resources provide a much more stable context in which a firm can develop its innovation activity and shape its markets in accordance to its own vision (Penrose, 1959; Wernerfelt, 1984; Wernerfelt, 1995; Grant, 1996; Prahalad and Hamel, 1990; Conner and Prahalad, 1996; Eisenhardt and Martin, 2000).

It is acknowledged that innovation as a process is a mixture of approaches, technological advances and market demands (Rothwell, 1992) thus the study perceives innovation as a combination of pathways towards the production or expansion of a technology or a service. As it is believed that it is not sufficient to consider a sustainable competitive advantage from a single firm, it is therefore necessary to take into account the conditions for sustainable competitive advantage in cooperation with other firms (Rasmussen, 2007, p. 1). A review of this stream of the innovation literature is presented in the following sections 2.1.2 and 2.1.3, highlighting the importance of multi-level investigation approach moving from the organisational boundaries to a multi-layered application of the concept.

### **2.1.2 Evolution of innovation processes**

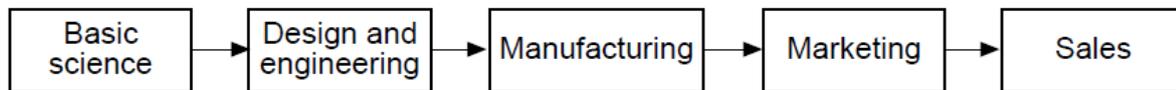
Rothwell's categorises the development of innovation perspectives over time, which suggests the movement from the closed to an open innovation model. To identify the manifestation of innovation and the fundamental enquiries into how it occurs and is managed, Rothwell provided a chronological framework to provide a better and more reliable interpretation of innovation theory. The process emphasises the embracement of traditional values and that the nature of the innovation process has evolved from simple linear models of the 50s to increasingly complex and interactive models (Tidd, 2006).

What drives the development or evolution of innovation is the growing complexity and pace of industrial technological change that forces firms to create new vertical and horizontal alliances and to pursue greater flexibility and efficiency in response to the various market changes (Rothwell, 1994, p.

7). Rothwell (1994) grouped the innovation theories into five historical generations regarding the manifestation of the process, in which innovation occurs in a series of sequential stages and recognises that networks are not simply an extend between doing everything in-house and of outsourcing, but it is also possible that an alternative way has powers that include both internal and external capabilities (Tidd, 2006, p. 9). Rothwell innovation theories are represented based on their chronological formation as follows.

- I. The technology push model of the 50s is a simple linear model that treats innovation as a sequential process that took place in distinct stages.

**Figure 1: Technology Push (First Generation)**

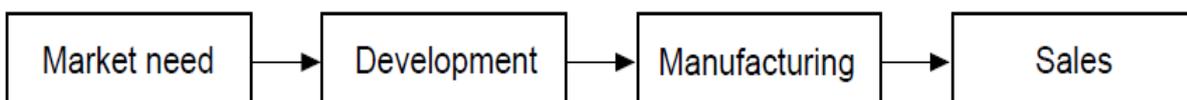


Source: Rothwell, 1994, p. 8

As the early practitioners of innovation utilised a linear mode towards their business approach (Bush, 1945), this model became the predominant application for value creation for several decades. Nonetheless, critics of the model argue that the linear process of the linear model miss-specifies the nature and direction of the causal factor at work (Kline and Rosenberg, 1986), as the emphasis on research and development pushes the market in a linear way.

- II. The market pull theory was developed in the 60s and places emphasis on the role of the marketplace and market research in identifying and responding to customer needs, as well as directing R&D investments towards these needs.

**Figure 2: Market Pull (Second Generation)**

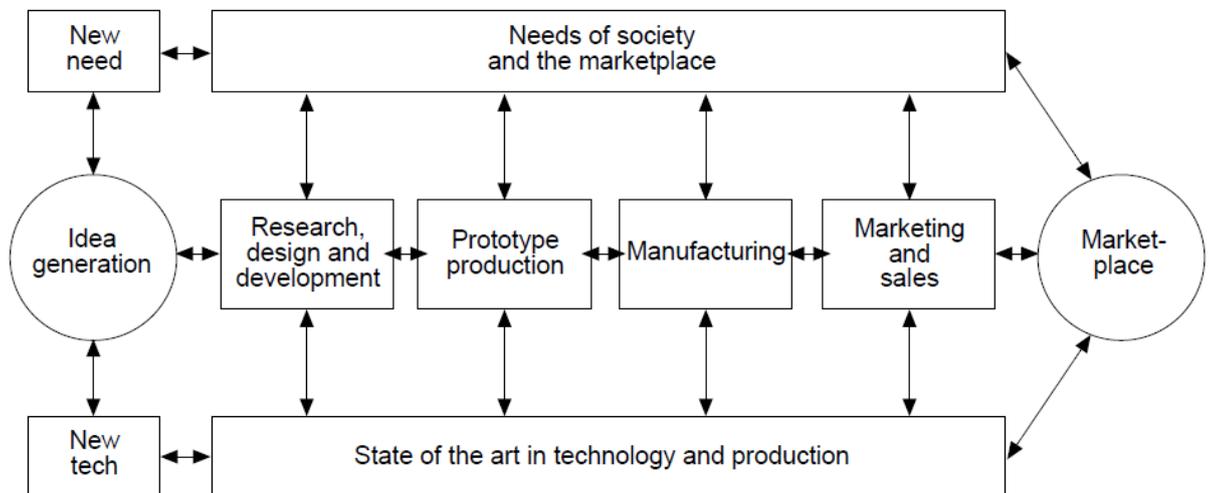


Source: Rothwell, 1994, p. 9

The second generation model presents a shift towards the demand side of the market, since marketing plays a significant role, as it is considered the source of ideas that provides direction towards R&D that has a reactive role (Hobday, 2005). None the less, a weakness of the model is that it clearly neglects the internal R&D and subsequently, firms are sealed in a system of incremental innovations to match the requirements of the market (Hayes and Abernathy, 1980).

- III. The coupling innovations process theory of the 70's and early 80's is a highly simplified version, as technological innovation comes from the coupling of market needs and technological opportunities.

**Figure 3: The Coupling Model of Innovation (Third Generation)**

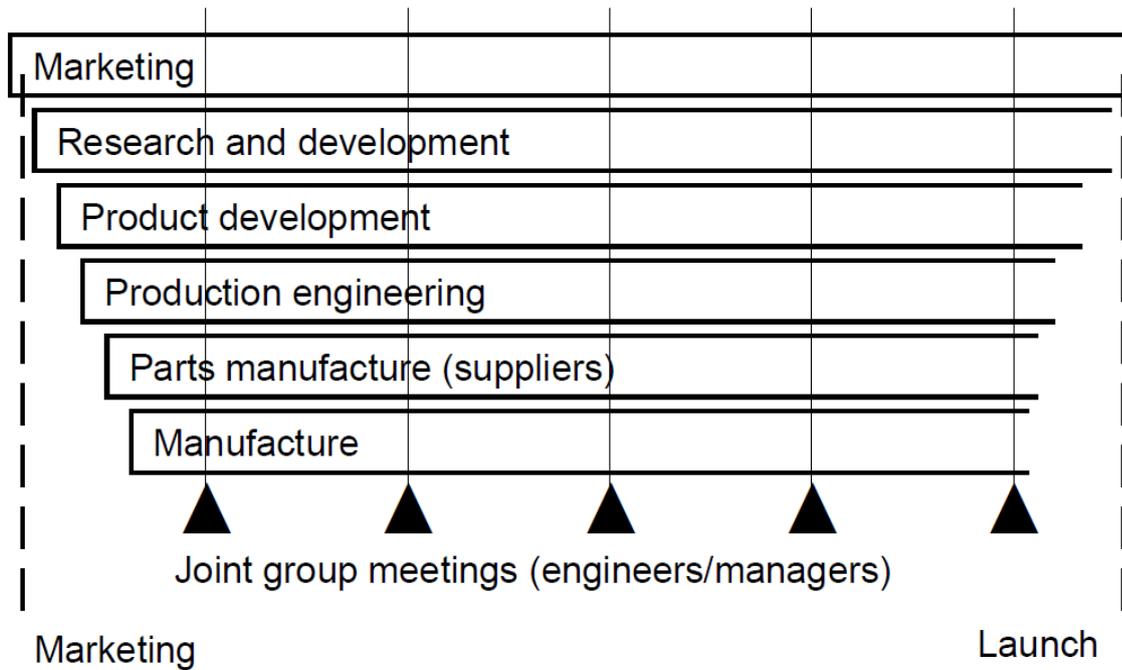


Source: Rothwell, 1994, p. 10

The coupling model, stresses the importance of technological innovations which are generated from the combination of market needs and technological opportunities (ibid). Although the third generation consists of the coupling of market needs and technological opportunities, in resembles the chain-linked innovation model of Kline and Rosenberg (1986, p. 289).

- IV. The integrated business process that was developed in the mid 80's is an integrated or parallel model that involves significant functional overlaps between departments and/or activities.

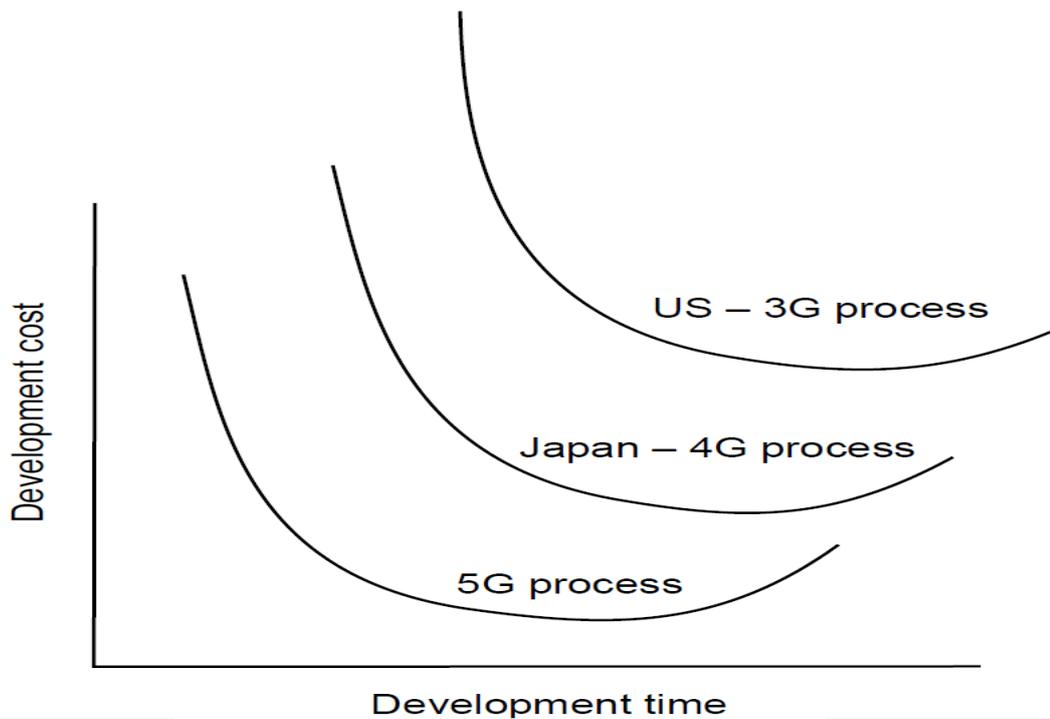
**Figure 4: Integrated Innovation Process (Fourth Generation)**



Source: Rothwell, 1994, p. 12

The fourth generation model came from observing the innovation of Japanese automobile companies (figure 4, Nissan innovation process) that involved significant functional intersections between departments and activities which improve time to market and development costs (Rothwell, 1994).

- V. The fifth generation process, which is based on the fourth generation process, emphasises the learning that goes on within and between firms, suggesting that innovation was generally and fundamentally a distributed networking process

**Figure 5: Product Development Time/Cost Relationships (Fifth Generation)**

Source: Rothwell, 1994, p. 14

The developments of the fifth generation model are extensions of fourth generation integrated models, which further emphasises on vertical relationships such as strategic alliances with suppliers and customers, and with collaborating competitors (Hobday, 2005). The fifth generation approach was brought about by time pressures on leading edge innovators which represent the electrification of innovation in economies and nations (ibid; Rothwell, 1994).

The five generation models place emphasis on the networking aspects of the innovation process (Freeman and Soete, 1997), and have been emphasised that by the late 1990s, companies were faced with the challenge of rapidly generating marketable products and services (Ahmed and Shepherd, 2010). This includes the customisation of products to accurately fulfil customer needs and simultaneously the necessity to acquire further resources and capabilities, which has worked as a driver to innovation management (ibid). Now, nearly 20 years on, there is a need to examine where other innovation models might be considered as the next generation of innovation theory. Innovation is currently

seen as a multilevel phenomenon, where not only individual characteristics and capabilities of firms, but also the environment in which innovation process occurs is crucial (Srholec, 2011).

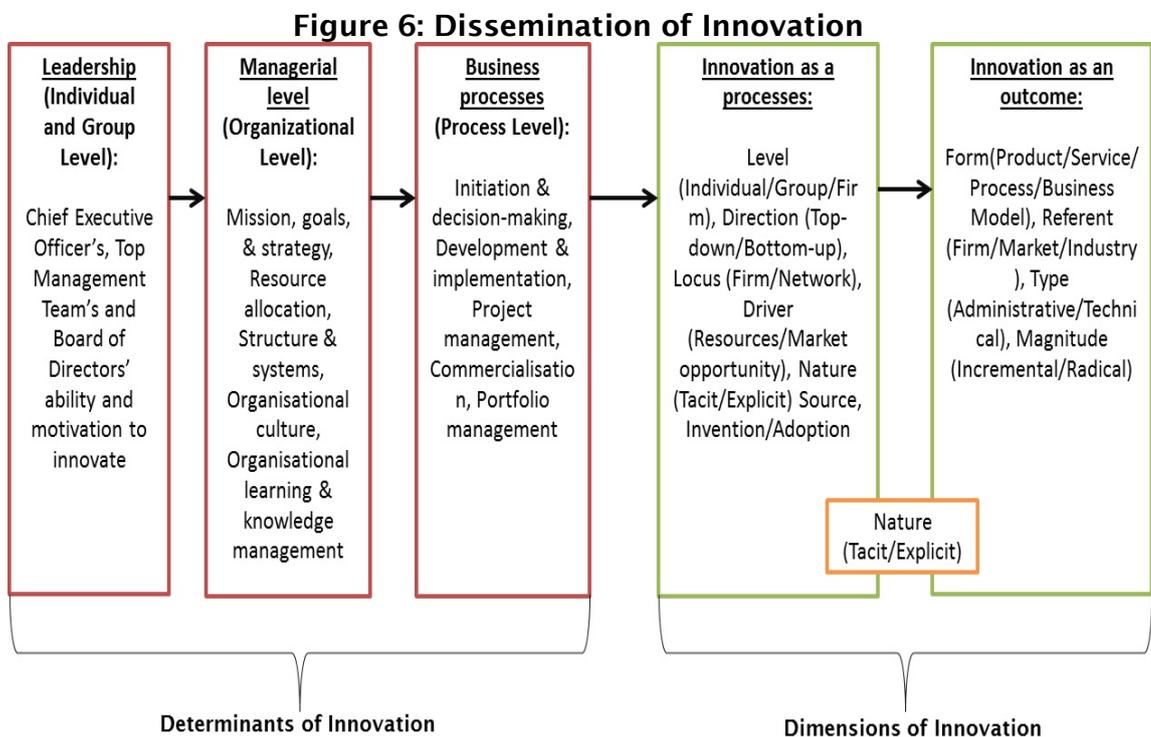
From Rothwell's innovation process theory, open innovation may well be the next innovation process as it reflects the perception that the innovation process has evolved from one dominated by large multi divisional, vertically integrated firms, to one in which both large and small firms each plays a significant role in a networked environment (Langlois 2003; Rasmussen, 2007, p. 6; Rothwell 1994). What has been noted is that the management of R&D has changed during the past decades, moving from an isolated view (first generation) to one that deals with more connected and complex situations (fifth generation) (Nobelius, 2004). Furthermore, Rothwell's 5th generation model clearly presages the notion of open innovation when seeking to identify prevalent features in current streams of innovation practices (Christensen, 2006, p. 42). Moreover, as the continuation of the fifth generation innovation process is characterised by the open model of innovation, scholars and practitioners are now paying a substantial interest towards open innovation as the next model of innovation (Gassmann and Enkel, 2004, p. 1). As with all emergent models of innovation, open innovation drives firms to draw on research and development that may lie outside their own boundaries (Chesbrough et al, 2006). As ideas can flow in and out of the company and can go to the market from either the traditional pathway of the firm or from new niche markets (Chesbrough, 2003a), open innovation is a clear movement from integration of systems and network process theory to an open theory, and it can be argued that this is the next innovation process theory.

### **2.1.3 Multi-layered studies in Innovation**

The interest in studying innovation lies in the fact that it consists of several important aspects that can be produced, captured and explained in different levels, such as firm, group, and individual levels of analysis (Crossan and Apaydin, 2010). Although the higher levels might be more comprehensive, they would necessarily include industry, national, or global levels, which are beyond the firm's control (ibid). In identifying what determinates innovation in

an organisation, several dimensions can be identified in which innovation can be manifested.

For the purpose of understanding a multi-layered system, figure 6 illustrates a multi-dimensional framework of organisational innovation in which the diffusion occurs in a series of relations between the individual (CEO), the organisation (mission, goals, and firm’s strategy) and the actual process (initiation and decision-making during a project), that delivers the innovation process and concludes with the formulation of the outcome (ibid, p. 1667). The particular model has been introduced to clarify that innovation as a process will always precede innovation as an outcome since the role of innovation as an outcome is both necessary and sufficient for a successful exploitation of an idea, whereas the role of innovation as a process is only necessary but not sufficient (ibid, p. 1669).



Source: Crossan and Apaydin, 2010, p. 1167

Within the field of innovation, several researchers addressed the importance of a multi-level perspective to address the characteristics of an innovation system, which is based on a micro-meso-macro layer, with numerous studies having been conducted to analyse innovation on the specific levels (Crossan and

Apaydin, 2010; Geels, 2002, 2004, 2005; Genus and Coles, 2002; Rip and Kemp, 1998; Smith et al, 2010). The multi layered focus stresses the importance of technological conceptualisation of a novelty which evolves from a tangible arrangement to a technical fix (micro), from a technical system to a regime (meso) and from a trend in technology to sociotechnical landscape (Rip and Kemp, 1998, p. 339). In support of the multiple layered method, Geels (2002, p. 1259) in his study for technological transitions in societal functions, clarified that the use of a multi-level viewpoint can be both an analytical and exploratory concept in understanding the complex dynamics of socio-technical change. This multi-level perspective conceives technological transitions as interactive processes of change at the micro-level of niches and the meso-level of socio-technical regimes, which is embedded in a broader landscape of factors at the macro-level (ibid). In order to clarify the use of multi-layered focus in the innovation literature, table 2 below identifies the studies in organisational innovation and open innovation that utilise such these descriptive approaches.

**Table 2: Level of analysis of the dimensions of Innovation and Open Innovation**

<b>Level of analysis</b>	<b>Innovation studies</b>	<b>Open Innovation studies</b>
Macro - Industry	Pavitt et al. (1989), Mansfield et al. (1981)	Toole (2014)
Meso- Macro	Downs and Mohr (1976), Henderson and Clark (1990)	Laurson and Salter (2006), Christensen et al. (2005), Chesbrough and Crowther (2006)
Meso - Organisation	Kimberly and Evanisko (1981), Dewar and Dutton (1986), Capon et al. (1992), King (1992),	Gambardella and Panico (2014), Lichtenthaler and Ernst (2009)
Micro - Within organisation	Thamhain and Wilemon (1987)	Chesbrough and Appleyard (2007)

Source: Compiled by Author and Camisón-Zornoza et al, 2004, p. 335

Table 2 describes the contributions of the multi-level method, to offer a specific type of analysis on a multi-level approach within the innovation discipline and the open innovation process in organisations. To begin with, the macro level studies stress the Inter-industry approach of the patterns of

development of innovation and its magnitude between industries, whereas the Intra-industry approach indicates the differences shown by organisations in the same industry, regarding to how the innovation is adopted. Now, on a meso-macro level, studies stress that the characteristics of the innovation do not differ with regard to its perception from an organisation or the industry. Moreover, on a meso level, studies capture the difference between innovative and non-innovative organisations based on their contextual, structural, and behavioural characteristics. On a micro level, studies assess the frequency of employed subunits in a department and the process of strategic business units (Camisón-Zornoza et al, 2004, p. 335). Section 2.2 highlights the development of the open innovation concept and its acceptance within practitioners and the academic literature.

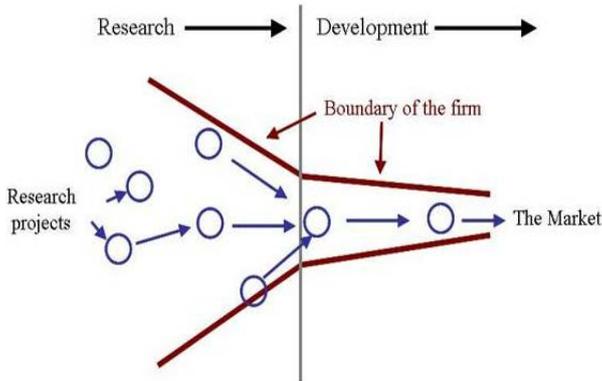
## **2.2 The Open Innovation Concept**

The concept of open innovation was introduced by Chesbrough in 2003 and since has gained widespread attention from practitioners who realised that companies that wished to commercialise both their own ideas as well as other firms' innovation, should seek new ways to bring their in-house ideas to market (Gassmann and Enkel, 2004). More than 10 years after its introduction, the open innovation concept has developed from a small number of innovation practitioners, mostly active in high-tech industries, to all business executives that experiment with a variety of new models for generating and commercialising innovation (Gassmann, Enkel and Chesbrough, 2010; West et al, 2014). At the same time, a small community of researchers and scholars have embraced the concept which is developed into an established research phenomenon within the field of innovation and management (ibid). Due to the increase in density of the innovation process in several industries, firms have to constantly absorb, integrate, and reconfigure knowledge to maintain a competitive advantage over time (Cillo, 2005).

The open innovation framework indicates the necessity of allowing ideas *“to flow out of the corporation in order to find better sites for their monetisation, and flow into the corporation as new offerings and new business models”* (Chesbrough, 2003a, p. xv). This means that valuable ideas can come from

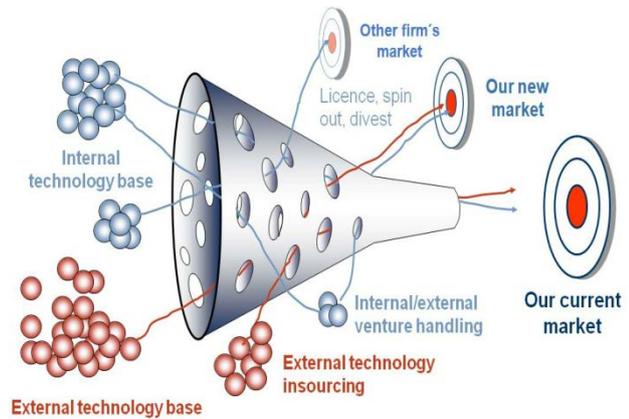
inside or outside the company and can go to market from inside or outside the company (ibid, p. 43). The following figures explicitly illustrate the processes of the traditional closed model in comparison with the new open innovation:

**Figure 7: Closed Innovation Model**



Source: Chesbrough (2003a, p. 31)

**Figure 8: Open Innovation Model**



Source: Chesbrough et al (2006, p. 3)

In representing the motion from closed to open innovation, table 3 indicates the notions of a closed innovation model compared to the open innovation model.

**Table 3: Open and Closed Innovation Characteristics**

Open Innovation	Closed Innovation
Not all the smart people work for the firm - Finding and tapping into the knowledge and expertise of bright individuals outside the firm is vital	The smart people in the field work for the firm
External R&D can generate significant value, and internal R&D is needed to entitle portion of that developed value	The profits from R&D operations, must be discovered, developed and shipped internally
There is no need to originate a research idea in order to profit from it	If it is discovered internally, it can go it to market first
Building an improved business model is better than getting to market first	If the firm is first to commercialise an innovation, it will win
If internal and external ideas are best utilised, it will be a winner	If the firm creates the most and best ideas in the industry internally, it be a winner

<p>There is a necessity to profit from external utilisation of internal intellectual property (IP) and buy external IP whenever it advances the internal business model</p>	<p>If the intellectual property (IP) is control, then the competitors cannot profit from a firms internal ideas</p>
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Source: Chesbrough (2003a, p. 38)

In the open innovation model, it is argued that a company commercialises its own ideas as well as ideas and innovations from other firms and pursues ways to bring its in-house ideas to market by deploying means outside its current businesses. For instance the boundary between the company and its surrounding environment can be accessible to external ideas (figure 8), enabling innovations to move more easily from in-out of the firm (ibid, p. 37). Moreover, in an open innovation environment, a company can utilise its own intellectual property through the necessary channels that exist outside the company and at the same time acquire and utilise external IP from sources outside the boundaries of the firm.

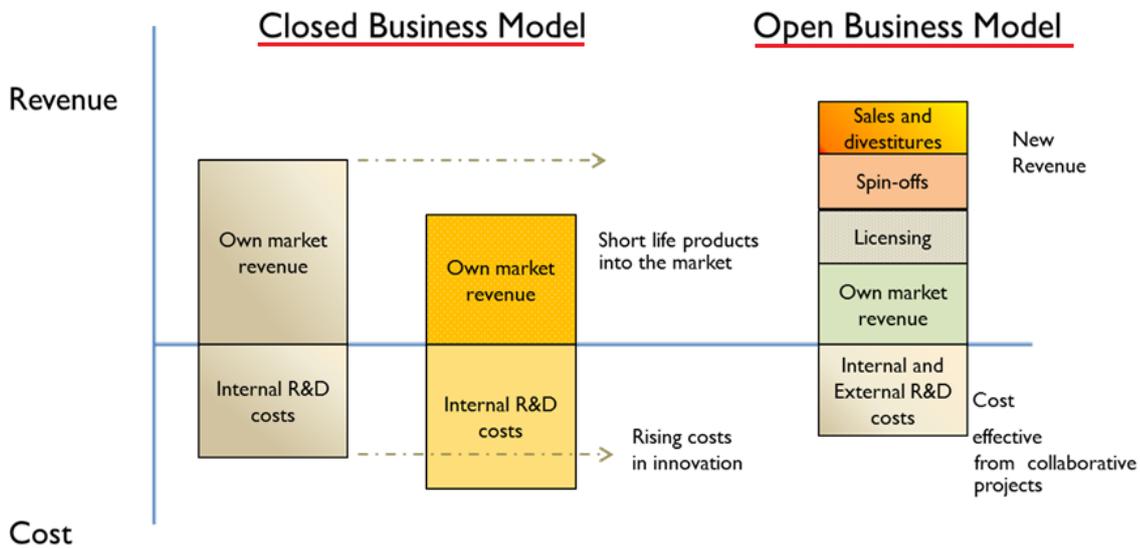
### 2.2.1 Open Innovation Business Models

In adopting an open innovation model several inside-out moves were indicated which a firm can adopt to help the perseverance of its own growth options, while simultaneously maintaining focus on its core operations (Chesbrough and Garman, 2009). Such adoptions are to become a customer or supplier of your former internal projects, and at the same time leaving to external sources the development your non-strategic initiatives. Moreover, making the intellectual property (IP) work harder for the firm and others can grow the firm's ecosystem, even when is not growing. By doing so, the firm creates open domains to reduce costs and expand internal and external participation (ibid). On the other hand, it has been argued that an open business model uses a new division of innovation labour for the creation of value and in the capturing of a portion of that value (Chesbrough, 2006).

For firms, one way of dealing with the pressure of highly competitive environments and short-life cycles, for example in high-tech products, is to collaborate with other firms for the development and manufacturing of new products (Dittrich and Duysters, 2007). A combination of leveraged cost and

time savings with new revenue opportunities confers powerful advantages for companies willing to open their business models. Figure 9 illustrates the different gains and losses by keeping the closed business model and adopting an open business model.

**Figure 9: Closed vs Open Business Model**



Adopted from: Chesbrough (2007)

It has been identified in recent years that more and more companies have been able to re-invent themselves with successful research and development projects (Pontiskoski and Asakawa, 2009). This allows them to minimise their costs and to simultaneously boost their profits, with the cases of Apple, Nintendo and Nokia being amongst the most famous examples (ibid). In many cases it has been suggested that firms can take even greater advantage of specialisation by ceding more control over decisions about the content of products to networks of participants (suppliers, customers, or both) who interact with one another (Bughin et al. 2008).

Open innovation requires the transformation of the firm's closed boundaries into a semi-permeable membrane that enables innovation to move easily *"between the external environment and the firm's internal innovation process"* (Chiaroni et al. 2011, p. 36). Dodgson et al. (2006), in their research of the Connect & Develop innovation model at Procter & Gamble, reported on the

feeling of many influential managers and highlighted the significant cultural and organisational change required to adopt open innovation. Regardless of its acknowledged importance, this particular feature of open innovation has been rather neglected by scholars so far and seems that there are no contributions taking an organisational change perspective to shed light on the adoption of open innovation. Therefore, the operation of open innovation would be better considered as a multi-phase organisational change process, since the elements of openness such as collaborations and in/out-sourcing occurs due to globalisation of markets, accumulated competition and internal business activities (Chiaroni et al. 2009).

### 2.2.2 Reception of the open concept

It has been observed that only very recently have a few attempts been carried out to study open innovation outside high-tech industries (Chiaroni et al. 2009). Although many of the tools utilised during open innovation practices such as licensing (Atuahene-Gima and Patterson, 1993; Tidd and Trewhalla, 1997; Arora, Fosfuri and Gambardella, 2002), joint R&D agreements (Arora and Gambardella, 1990; Steensma and Corley, 2000; Ritter and Gemünden, 2003), minority investments and corporate venture capital (Ernst, Witt and Brachtendorf, 2005; Dushnitsky and Lenox, 2005a; Dushnitsky and Lenox, 2005b; Markham et al. 2005), or spin-offs (Birkenmeier, 2003; Lichtenthaler, 2006) were well established before the term took root in theory and practice, however, open innovation is more than just the sum of its parts (Herzog, 2008). Table 4 summarises some of the principal research perspectives regarding the openness of firms in stimulating their innovation process.

**Table 4: Open Innovation propositions**

Author	Focus
Cusumano, Mylonadis, and Rosenbloom (1992)	Explore the effects of strategic manoeuvring and mass-market dynamics among firms such as planning efficient manufacturing operations, organising alliances for production and distribution.

von Burg (2001)	The focus on the structure of technological communities: Structure and relationship between the external network of suppliers and the innovating firm is critical to understanding which technology and firm wins the race for determining the industry wide technological standard.
Chesbrough (2003a)	Open innovation is a concept that assumes that firms: Can and should use external ideas as well as internal ideas, and internal and external paths to market, to advance their technology and innovating with partners by sharing risk and reward.
von Hippel (2005)	How individuals can participate in the development of products they use as manufacturers should re-design their innovation processes and seek out innovations developed by users.
Boudreau (2007)	How opening a platform affects innovation, which is central to strategy and policy in many high tech industries.

Compiled by author

The conception is clearly moving from an internally focused innovation model to an open and integrated model in which alliances and networks can help an organisation in expanding its knowledge and efficiency by looking outside the traditional boundaries of the firm, but nonetheless it should be consider as a work in progress rather than a given and readymade approach (Trott and Hartman, 2009, p. 731).

### 2.2.3 Methodological approaches in Open Innovation

Several methods have been used to measure open innovation such as grounded theory that supports *“the discovery of theory from data systematically obtained from social research”* (Glaser and Strauss, 1967, p. 2). This particular method utilises an inductive theory discovery methodology that allows the researcher to develop *“a theoretical account of the general features of a topic while simultaneously grounding the account in empirical observations or data”* (Martin and Turner, 1986, p. 141). West and Gallagher (2006) discussed the method of grounded theory and used it to investigate

how open source addresses three management challenges of open innovation; motivation, incorporation, and maximisation. Their study utilised qualitative data in an inductive method to draw theory from a set of case studies using primary and secondary sources (ibid, p. 90). West and Gallagher (2006) concluded that software firms seem to embrace open innovation only when there is no alternative, and firms support open source communities as a part of their intentional open innovation strategy (West and O'Mahony, 2008, p. 146).

Open innovation was introduced by scholars in the field of technology and innovation management, and is currently cited in "*strategy, general management and organisation behaviour journals*" (Gassmann, Enkel and Chesbrough, 2010, p. 215). At present, open innovation has changed its status from the research interest of a few to an established research area, with the majority of studies being based on grounded theory (constructivism - inductive reasoning) or quantitative statistical methods (positivist - deductive reasoning). Now 10 years since its introduction, the majority of studies are of an exploratory nature (De Wit et al. 2007; Hagedoorn and Ridder, 2012; Van de Vrande et al, 2009), thus a more critical perspective will be more suitable to explain rather than describe the concept of open innovation. As the aim is to capture what opportunities and barriers open innovation creates to firms, the use of critical realism as a paradigm of choice will allow the examination of the causal mechanism and emergent powers that drive objects such as individuals in adopting (events) such strategies and models (Sayer, 1992).

#### 2.2.4 Examples of Open Innovation adoption

As mentioned above, open innovation has become the centre of interest for many companies actively searching for new ways of improving internal efficiency with minimal costs. Table 5 illustrates several cases which firms adopted open innovation strategies and models, and the profits they retrieved through the particular approach.

**Table 5: Firms Embracing Open Innovation**

Nestlé	Embraced new ideas, competencies, and	Switzerland - Food processing
--------	---------------------------------------	-------------------------------

	ways of thinking about collaborations with external partners	
3M	Embraced open innovation and profited from an increased R&D agility and effectiveness and a decreased risk exposure	USA - Conglomerate
Eli Lilly	Open innovation Drug Discovery interface, assisted external investigators securely upload and submit structures of their compounds to be evaluated for novelty and reasonable drug-like characteristics	USA - Pharmaceuticals
Pfizer	Designed a partnering model to accelerate drug discovery and development	USA - Pharmaceuticals
GlaxoSmithKline (GSK)	Launched its open innovation initiative early in 2010 by starting its first "Open Lab"	British - Pharmaceuticals
Johnson & Johnson	Leveraged the power of its entrepreneurial	USA - Pharmaceutical/Health care/Cosmetics

	employees through its Innovation Sandbox initiative	
Apple	Outsourced certain aspects of its product that enabled a focus on different aspects of the product such as the interface and commercial areas of the “iPod”	USA - Consumer Electronics
Nintendo	Integrated with its customers in order to understand and create a unique gaming experience the “Wii”	Japan - Consumer Electronics
Nokia	Overcame the “Not invented here” syndrome, which allowed the firm to partner with external organisations in developing a new novelty the “n-series”	Finland - Telecommunications Equipment Company
Goldcorp	Used open innovation by “Put it into a file and share it with the world”, which resulted in increasing its target productivity by 50%	Canada - Gold Mining

General Mills Worldwide Innovation	Connected employees with inventors, academics, entrepreneurs, suppliers, customers and consumers throughout the innovation process	USA - Food processing
Unilever	Looked for new ways to work with potential partners	British/Dutch - Moving Consumer Goods
GOJO Industries, Inc.	Applied open innovation through technology and strategic partnerships to reduced development costs and accelerate future generation products	USA - Skin Care Products
AOL	Used an open source strategy	USA - Internet/Telecommunication/Media
The Clorox Company	Brought ideas from people and organisations outside the firm and established relationships and partnerships with inventors, universities and even other	USA - Food/Chemicals

	companies	
The Hershey Company	Allowed mutual success and accurately defined the scope and scale of the partnership	USA - Foods
Intel	Exploited the level of knowledge and venture capitals, by creating programs to in-source external technology and applied investments of corporate venture capitals in start-up companies	USA - Semiconductors
IBM	Concentrated on generating new revenues from semiconductor business, IP licensing and open source software initiatives	USA - Computer hardware - software, IT
Procter & Gamble	Licensed or acquired products from other companies and brought them to market by actively seeking for external ideas and technologies through an extensive network	USA - Consumer Goods

	of researchers	
Mars, Inc.	Outsourced its findings into the public domain in order to accelerate advances in the field	USA - Confectionery
Siemens AG	Integrated external problem-solvers into the innovation process	Germany - Conglomerate
ConocoPhillips	Created an open innovation competition to identify novel, clean, reliable and affordable sources of energy	USA - Oil/Gasoline
PepsiCo	Developed partnerships securing exclusive rights to proprietary technologies and accelerating speed to market for advanced solutions	USA - Foods/Beverages

Source: CoDev conference 2012; Chesbrough, 2003, 2006, 2007b; Hunter and Stephens, 2010; Pontiskoski and Asakawa, 2009; and Tapscott and Williams, 2006.

What has been recognised is that open innovation requires managers to identify the core capabilities of the firm, which needs to be adopted as the main focus is to expand their productivity (Pontiskoski and Asakawa, 2009).

Nonetheless, the concept is seen by the academic literature with scepticisms and section 2.3 presents critique of the open innovation concept and expands the presence of fads in the management literature.

### **2.3 Boundaries and Barriers**

There has been some controversy and criticism regarding the open innovation framework, noticeably from Trott and Hartmann (2009) and Mowery (2009), who suggested that the concept of open innovation seems to have emerged without much critical analysis or definition, noting that its elements are evident in other, earlier conceptions of innovation. These authors argued that Chesbrough (2003a, 2006) creates a false contrast by claiming that open innovation is the only alternative to a closed innovation model and consequently offering the wrong impression which might result in firms blindly following these principles without fully understanding the underlying assumptions and principles of the approach. Chesbrough argued that “business model innovation is vitally important, and yet very difficult to achieve” and therefore barriers to changing the business model are real, and tools such as maps are helpful, but just not enough. Arguably, as the open innovation concept consists of pre-existing elements within the innovation literature (Trott and Hatrmann), it is not surprising that doubts are emerging concerning the effect, application and novelty of the model.

Open innovation has been covered in different areas such as vertical specialisation (involvement of market relationships), as well as an increased role for firms specialising in the “upstream” phases of the innovation process (Mowery, 2009). This exposes the fact that several open innovation components can be found in the US industrial research system in the late 19th and early 20th centuries (Lamoreaux and Sokoloff, 2005), underscoring the extent to which “open innovation” itself may not be an entirely novel phenomenon. Similarly, Groen and Linton (2010) highlighted the need for a clear definition of open innovation by pointing to the potential similarity of the concept with the older term, supply chain management (Lichtenthaler, 2011).

The introduction of open innovation is not the first set of support that recognises the importance of external sources of technology and knowledge

(Acha, 2008). Trott and Hartmann (2009, p. 715) argued that the open innovation concept represents “little more than the repackaging and representation of concepts and findings presented over the past forty years within the literature on innovation management” and is based in pre-existing notions such as:

1. Increased size of R&D projects due to external influences- Pearson and Ball (1979).
2. The network model of innovation - Rothwell and Zegveld (1985).
3. Characteristics of technically-progressive firms and the quality of incoming information - Carter and Williams (1951).
4. External linkages in acquiring information and knowledge networks from outside the organisation - Allen and Cohen (1969).
5. 5th generation model of R&D management, emphasising the need for increased external focus utilising information technologies - Rothwell (1992).

As a result, open vs closed business model creates an intuitive dichotomy between “*the old way of doing research and development and the new way which adopts the principles of open innovation*” (Trott and Hartmann 2009, p. 728). As the argument of the contradiction between closed innovation and open innovation may be true in theory, it may not actually exist in industry; certainly not to the extent of the examples introduced by Chesbrough (2003a). It is also helpful and motivating as a policy to introduce a “*new concept such as open innovation to companies that are already most of the way there*” (ibid).

Notably, intellectual property is difficult to protect and the benefits from innovation are difficult to appropriate. This has led Dahlander and Gann (2010, p. 699) to argue that even though openness can result in resources being made available for others to develop, it also creates a nervousness which makes the whole concept difficult to control. Moreover, it has been argued that a real paradigm shift is irreversible and differs from fashion and science hypes in terms of its long-term impact (Gassmann et al, 2010).

Savitskaya et al, (2010) identified that during the in-bound innovation companies face several barriers, such as:

- “Not Invented Here” Syndrome
- No adequate technologies on offer
- Resources and time drainage
- The fear of losing the innovation ability

At the same time, several barriers have been identified for the out-bound innovation such as:

- “Not Sold Here” Syndrome
- Complexity of Intellectual Property Rights, fear of breaches and IP violations
- The difficulty of finding customers
- Lack of marketplaces for technologies

Although several studies have been made around the open innovation framework, companies are not yet massively embracing the new concept of “open innovation” (De Wit et al. 2007, p. 17). Moreover, several arguments have been made suggesting open innovation is a fad, as there is a concern that once a field grows rapidly it may only become a short-term fashion and hype (Gassmann, Enkel and Chesbrough, 2010).

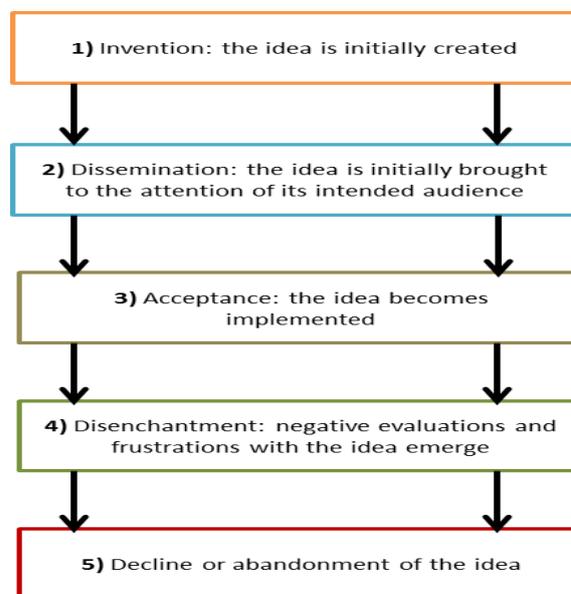
Academics and scholars in the field of innovation are trained to be rightly unconvinced of the introduction of new frameworks and concepts. As such concepts often consist of little more than fads and fashions (Abrahamson, 1996), which at best, can distract managers from other important activities, and at worst, might damage companies and individuals (Chesbrough, 2006, p. 3). During the boom of the 1990s management theory exploded into a series of fads, a phenomenon that had a lot in common with the latest fashion “diet” (Kennedy, 2007, p. xi).

Fads are defined as “managerial interventions which appear to be innovative, rational, and functional and are aimed at encouraging better organisational performance” (Carson et, al. 1999). The history of fads and fashions in management techniques are evident from what scholars have called a management technique’s popularity wave (Abrahamson, 1991; Abrahamson and Eisenman, 2008; Burns and Wholey, 1993; Kieser, 1997; Carson et al,

2000; Scarborough and Swan, 2001). Usually, the terms ‘fads’ and ‘fashions’ are used to label evolving managerial practices but typically neither comprehensively express the terms nor specify the criteria for labelling something a fashion (Ashkenas, 1994; Baillie, 1995a; Currie, 1999; Gordon, 1997; and Stipp, 1996). As a result, fads and fashions have been variously conceptualised as potentially useful (Bohl et, al, 1996) or as useless (Donaldson and Hilmer, 1998); as important (Dreilinger, 1994) or as trivial (Gordon, 1997); as having mass appeal (Abrahamson, 1991) or as adopted only by a frenzied few (Kieser, 1997). A managers tendency to tenaciously latch onto unproven conjecture (labelled as "fashion consciousness" by Drucker and Davenport 1997), despite the widespread experience of failure with previous fashions (Ashkenas, 1994), has raised the question of whether managers are simply attempting to out-source critical thought (Carson et al. 2000). Fashion bashing itself is becoming fashionable, leading one writer to question whether “fad less management might be the next management fad” (ibid, p. 1143).

Fads are by definition short-lived as they exist through a short period of engagement whilst there is an overstated enthusiasm for a particular idea or practice at that particular time (Furnham, 2004). Management fashions (Gill and Whittle, 1993) are seen to progress through a series of discrete stages:

**Figure 10: Phases of Management Fads**



Source: Gill and Whittle, 1993

Regarding the open innovation concept, it was debated that the emergence of the notion brought with it the risk that it would be a managerial fad rather than a stable theory (Faems 2008, p. 334-335). Nonetheless, it was observed that when managers were using the word diversity in their organisation, they were using it as a buzzword because it framed a set of decisions in a way that protected the particular managers from potential criticism (Cluley, 2013; Prasad et al, 2011). This was due to the absence of a sound framework, and was argued that if the open innovation paradigm wants to be more than a managerial fad, it should be made clear under which circumstances the “open innovation paradigm” is not a relevant perspective (ibid).

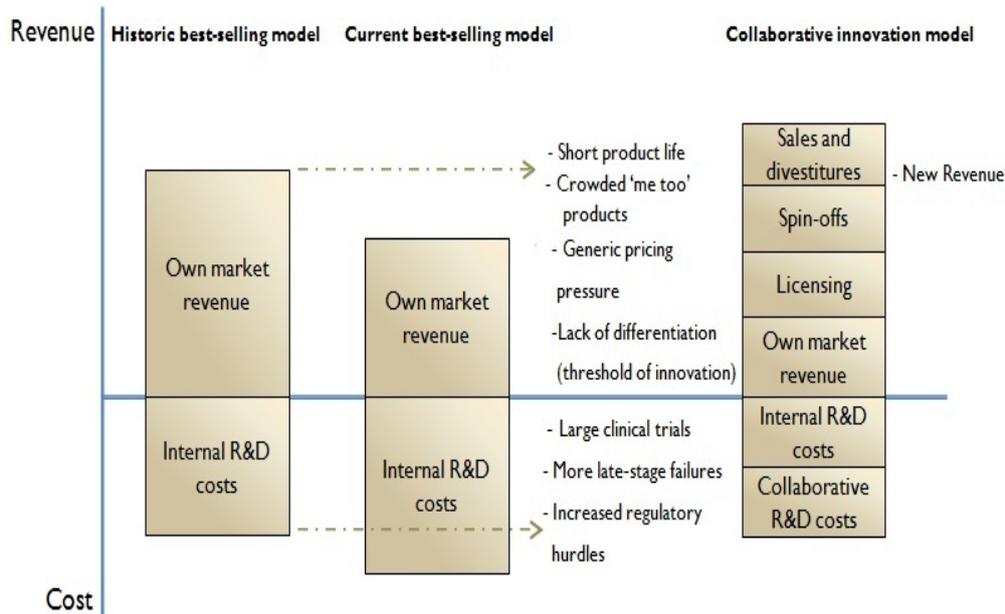
The literature of open innovation keeps growing and it is becoming more of a strategy rather than a buzzword, as a number of major examples contribute to the concept's expansion (Van der Meer, 2007, p. 201). Since its introduction, several studies have shown the successful adoption of open innovation within the management discipline. Furthermore, it has been validated by the fact that it is now treated as an Innovation strategy, leadership and organisational structure that offers a rich source of information for additional discussion, analysis and possible recommendations for innovation managers (Giannopoulou et al. 2010). None the less, the sharing aspect and widespread adoption of open innovation seems to be novel among the studies in the management discipline, thus explaining its continuation and application by many industrial sectors. The following section 2.4 presents the contribution significance of the adoption of open innovation within the Biopharmaceutical industry.

## **2.4 Open Innovation in the Biopharmaceutical Industry**

During the late 1990s and early 2000s several mergers took place in the global pharmaceutical industry for market control: Pfizer and Warner-Lambert in 2000; Glaxo Wellcome and SmithKline Beecham in 2001; and Pharmacia in 2002. More recently however, pharmaceutical companies seem to favour looser contractual agreements, such as collaborations and licensing deals. To confront today's greatest pressing issues, pharmaceutical companies are investigating new and innovative methods, as the overall transaction value of

collaborations within the pharmaceutical industry has increased almost threefold since 2000, reaching over \$100 billion by 2004 (Gassman et al. 2008, p. v). Melese (2009), illustrated how the open innovation model works for pharmaceutical companies, which includes the traditional model and the transition to an open business model.

**Figure 11: Open innovation during the Pharmaceutical process**



Adopted from: Melese et al (2009, p. 502)

Several companies adopted the new way of dealing with innovation, for example Eli Lilly who spun out from “InnoCentive” in 2003, a worldwide web problem-solving platform designed to connect companies with research challenges to potential solution providers (Munos, 2006). In addition, it introduced the Phenotypic Drug Discovery Initiative in 2009, by making the company’s assays and expertise openly available to academic institutions with the intention of sourcing new collaborations and compounds (Hunter, 2010). Likewise, Pfizer openly allowed other firms and organisations to screen against their internal compound library to attract possible solutions to their compounds, therefore cutting back their R&D costs dramatically (ibid).

Similarly, a group of major Biopharmaceuticals, including GlaxoSmithKline (GSK) Merck, Novartis and Sanofi, adopted open innovation through initiatives such as the WIPO Re:Search. This is an open lab project that allows external

researchers to access GSK compounds and facilities for drug discovery research on diseases in the developing world (Sheridan, 2011). Moreover, biotechnology firm Genzyme decided to bring in technologies from the outside and develop them in-house from its licenses technology (Chesbrough, 2007b). This turned its external ideas into a selection of novel therapies that delivered important cures for previously untreatable rare diseases, and built a financial record in an industry where profits are difficult to achieve (Pisano, 2006). P&G, for example, is best known for its embrace of outside-in open innovation via its Connect+Develop initiative in 2006, by opening up its business model to licensing out technologies for others to use (Chesbrough, 2012).

Recently, researchers debated that as Biotechnology is one of the emergent sectors its development is largely based on the creation of research-intensive SMEs (Mangematin et al, 2003). There are large sample studies showing the benefits of open innovation policies, such as Laursen and Salter (2006) who examined the relationship between the openness of manufacturing firms' external search strategies and their innovative performance, but the study focuses on showing how large sized firms benefit from these policies. Even though large firms might differ from small firms in terms of open innovation adoption, only a limited number of studies within small firms exist (Chesbrough et al. 2006, p. 40). This is due to the fact that traditionally, open innovation has been analysed mainly within the context of large, multinational and technological firms based on the examples of Xerox PARC, IBM, Intel, New Ventures Group (Van de Vrande et al. 2009). Section 2.4.1 describes the presence and application of innovativeness within the context of the Biopharmaceutical sector, and denotes the significance open innovation offers to the sector.

### **2.4.1 Innovation in the Biopharmaceutical Industry: Role of Biotech and Pharmaceutical companies**

Like innovation in fields such as information technology, bio-pharmaceutical innovation has a variety of impacts on society. Not only can it increase the Gross Domestic Product through its short-term employment effects but also effectively improving public health and longevity (Murphy and Topel 2003a, b; Cutler 2004), as well as the long-term economic growth (Sloan and Hsieh, 41

2007). Biotechnology is a science-led industry with R&D cycles and product lead times with a duration of up to 20–30 years since the development of new techniques and opportunities in the science (Champion, 2001), and the on-going commercialisation of the scientific research, which meant that it was recognised worldwide as a critical sector to national economies (Hine and Kapeleris, 2006).

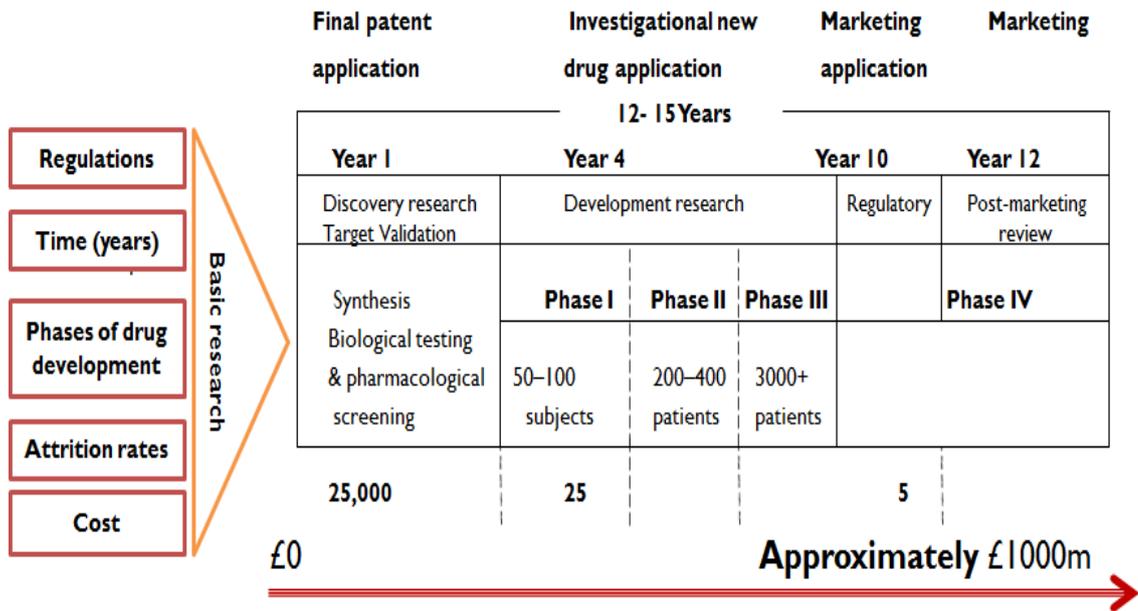
As the economic downturn hit most sectors on a global scale, some industries increased their R&D spending, such as the pharmaceuticals and biotechnology, electronic and electrical equipment, and chemicals–managed (BIS - The 2010 R&D Scoreboard). Arguably, the global financial crisis created an uncertainty in the industry which resulted into more and more downsizing and budget cuts (Talaga, 2010, p. 1399).

Although the performance of the global pharmaceutical market was more positive in 2010 than 2009, the fundamental dynamics of the innovation cycle and funding pressures of pharmaceuticals will result in low-single number growth over the next five years (Pharmaceuticals & Biotech Industry Global Report - 2011). The pharmaceutical industry is hugely valuable for its contribution to the UK economy and has a vast effect on health improvement (Sloan and Hsieh, 2007). However, the various hurdles produce the necessity to validate alternative methods of improved innovation process, as the development of new pharmaceutical compounds takes between 12 and 15 years (see figure 12), where just 5 out of 25,000 compounds tested in the laboratory are actually approved by regulatory authorities following clinical testing<sup>1</sup>.

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<sup>1</sup> Did you know Facts and figures about the pharmaceutical industry in the UK Second edition 2011

Figure 12: Pharmaceutical Compound Process



Adopted from: ABPI 2011<sup>1</sup>

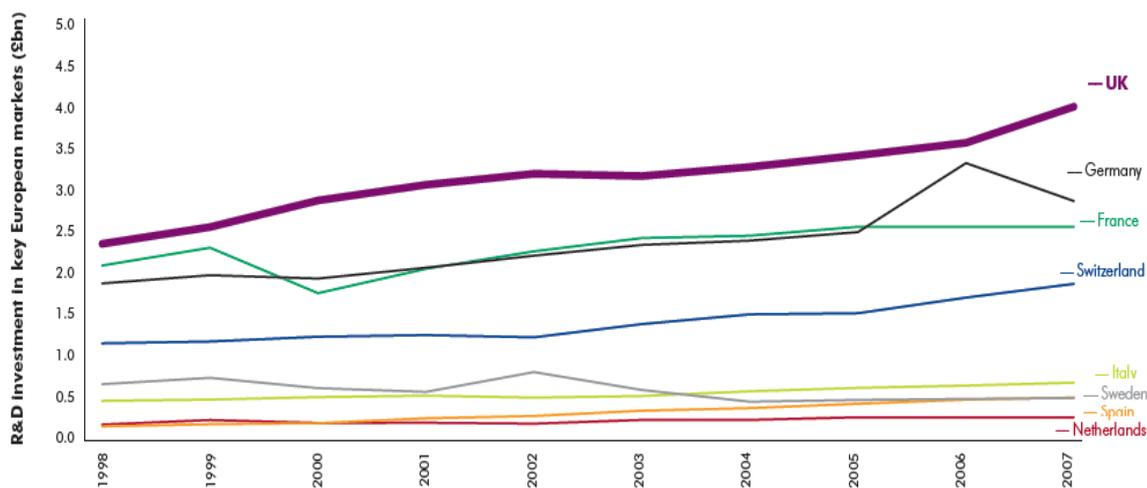
In the midst of financial downturn, the pharmaceutical industry, who is one of the most important sectors for the UK economy is under severe financial pressure (Paul et al, 2010, p. 203). This ranges from environmental issues, to losses of revenue due to patent expirations, to increasing costs and demanding regulatory requirements which pushes the total costs to the roof (ibid). In the health sciences, innovations have caused dramatic changes in the ability to treat disease and improve the quality of life (DiMasi et al, 2003, p. 151).

The significance of pharmaceutical companies in terms of research purposes is predominantly due to the long-term strategic shifts in the scientific and commercial dynamics of the sector, as rapid changes in scientific position occur frequently (Casper and Matraives, 2003). Such changes can be the increase of innovation costs (for example, the cost of developing a new drug (see figure 12), the changes in marketing methods and the shifting of R&D to focus on chronic rather than acute illnesses, in part due to the rapid aging of the population (Matraives, 1999). The pharmaceutical industry invites a more profound analysis of complex industry dynamics, which allows a researcher to examine how external structural changes withstand the competitive process, such as to restrain a firms' strategy (Casper and Matraives, 2003). The

Pharmaceutical and Biotechnology industries have a huge influence in the UK, as the life science sector plays a crucial role as a driver of social prosperity and economic growth<sup>2</sup>.

The pharmaceutical industry has a major impact on the economy as the daily R&D investment of £13.6 million is the biggest of any other industry within the UK<sup>3</sup>. In terms of employment, the pharmaceutical and biotechnology industries in 2010 employed 78,000 and 24,280 respectively out of the 166,280 total numbers of employees in the life science sector. When compared to 146,700 in 2008, this is an increase of 13.34%, with an annual turnover of £35.6 billion<sup>4</sup>. Biomedical science represents a financially important sector with more than 9% of UK exports worth £21 billion and 28% of all UK business Research and Development (R&D) spending<sup>5</sup>. Figure 13 shows the research and development expenditure among the leading European countries, with the UK having the largest amount of investment.

**Figure 13: R&D investment in European markets**



Source: ABPI, Facts and figures about the pharmaceutical industry in the UK - Second edition 2011

<sup>2</sup> Strength and opportunity 2011 - Annual Update - December 2011

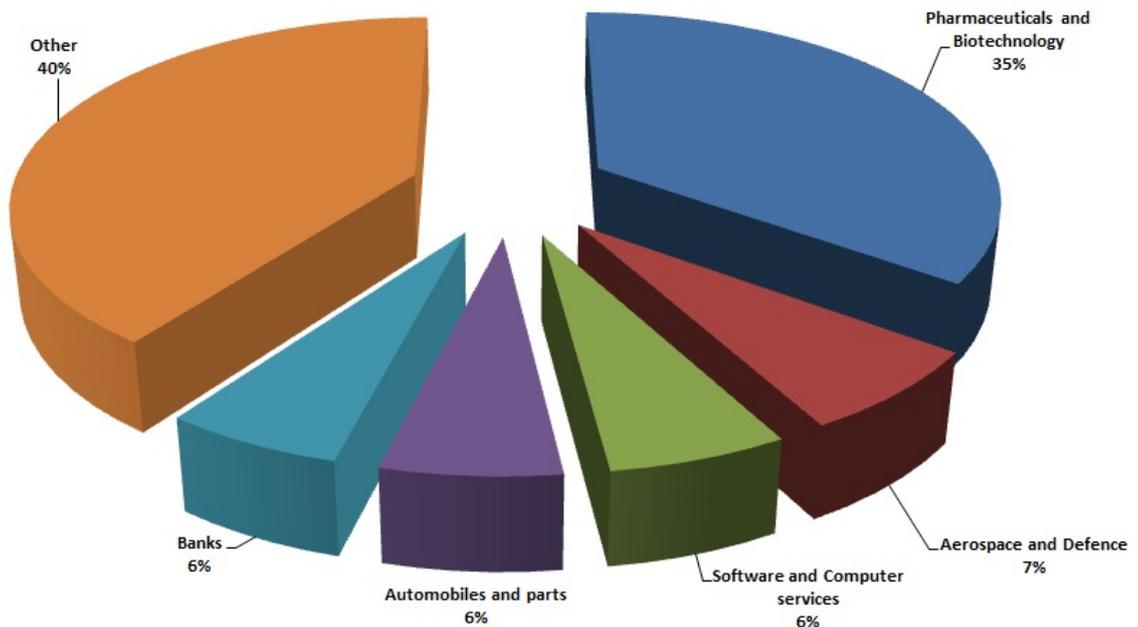
<sup>3</sup> Facts and figures about the pharmaceutical industry in the UK - ABPI Second edition 2011 / Strength and opportunity 2011 - Annual Update - December 2011

<sup>4</sup> Strength and opportunity 2010 / 2011 - Annual Update - December 2010 / 2011

<sup>5</sup> Office of National Statistics, 2009

The UK is investing in innovation and growth directly because the government recognises the need to invest in innovation and healthcare by allowing the £4.6bn science budget to be increased in terms of annual health spending<sup>6</sup>. Melese (2009, p. 502) argued that the existing model of Biopharmaceutical innovation is financially unsustainable, as the cost of internal innovation was exceeded by product revenues and since the cost of internal innovation has increased with little impact on revenues. On the other hand, the collaborative innovation model allows companies to look outside their boundaries for technological ideas and intellectual property, which leads to new revenues through licensing, spin-offs or sales and investments. With the use of the open model, the costs of internally developing innovation are reduced when companies bring in new technologies through collaborations. The following figure illustrates the distribution of UK research and development in 2009.

**Figure 14: UK R&D Distribution**



Source: Pharmaceuticals & Biotech Industry Global Report 2011

Despite all the mergers and acquisitions in this sector, large pharmaceutical companies are found to have a negative impact on innovative performance, probably due to the post-merger intemperance of human capital and

<sup>6</sup> Investing in UK Health and Life Sciences - December 2011

integration problems (Ornaghi 2006, p. 30). Technologies such as information and communications technology (ICT), biotechnology and new materials are becoming a great driving force of generating competitive gains and financial success for companies in a wide range of industries (Vanhaverbeke and Cloudt, 2006). This stresses that the only reason behind firms teaming up is technological difficulties, which leads to an increasing number of firms turning to open innovation adoption is the need to diversify their business models (Rafols et al. 2012). As biotech and pharmaceutical firms find it hard to research and develop their ideas and compounds, knowledge brokers and agents can play an important role as intermediates between companies, institutions and regulatory organisations.

#### **2.4.2 Knowledge Brokers in the Biopharmaceutical Industry**

In recent years, knowledge brokers have been characterised as modern innovation factories as their output consists solely of innovative solutions to novel problems (Hargadon, 1998, p. 210). Over the last decade, knowledge brokering has gained increasing importance, as their behaviours and practices became used to initiate and develop the use of knowledge by creating links between researchers, policy makers, managers and practitioners (Ziam et al. 2009). Knowledge brokers are recognised as people or organisations that move knowledge around and build relations between researchers and their various viewers (Meyer, 2010). Moreover, they work closely with their business customers to provide specific innovation solutions; traditionally they have taken the form of innovation and design consulting firms (Sutton 2002; Hargadon 2003). Lomas (2007) identified several attributes and skills of knowledge brokers to be:

- A. Entrepreneurial skills (networking, problem solving, innovating)
- B. Trust and creditability
- C. Clear communicator
- D. Understand the cultures of both the research and decision making environments
- E. Able to find and assess relevant research in a variety of formats
- F. Facilitates, mediates, and negotiates

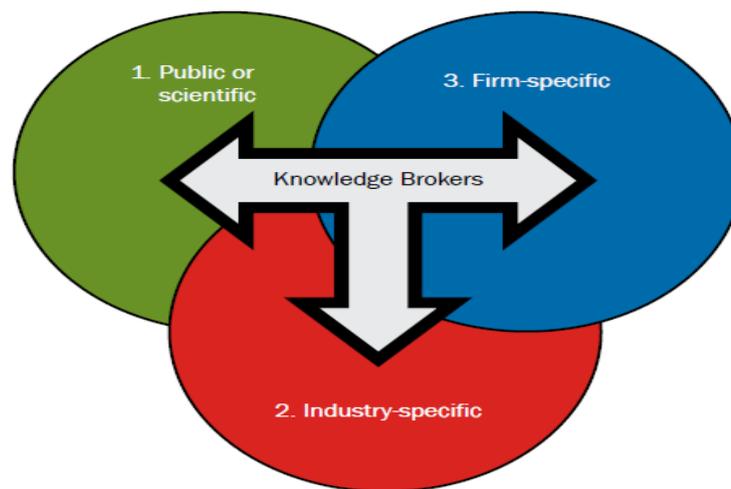
G. Understands the principles of adult learning

Source: Clark and Kelly, 2005; Canadian Health Services Research Foundation (CHSRF), 2003

Positioned on the line between the researchers and decision makers, knowledge brokers are seen as the human force behind: knowledge transfer; finding, evaluating and interpreting evidence; facilitating collaboration; and identifying emerging research enquiries (CHSRF 2003). Sousa (2008) argued that knowledge brokers can act as intelligent change agents that encourage change and increase the number of external exchanges in a dedicated way, by stimulating innovation while creating momentum for action. With regards to skills and knowledge of brokers, Leonard-Barton (1995) further identified three major types (see figure 15):

- Public-scientific
- Industry specific
- Firm-specific

**Figure 15: Knowledge brokers and types of knowledge**

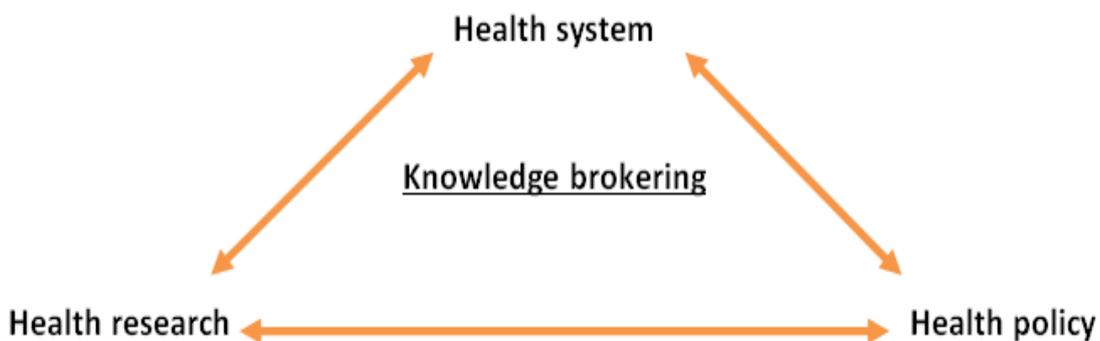


Source: Sousa, 2008, p. 19

Mainly the responsibilities of knowledge brokers are to establish and maintain links between researchers and their audience through a suitable translation of research findings (Allen and Cohen, 1969; Lomas, 1997). In addition to their

technical knowledge, knowledge brokers possess what could be called relational knowledge or knowledge about knowledge, allowing them to know what others know, while providing the managerial and physical tools to access that knowledge (Sousa, 2008, p. 19). van Kammen et al (2006) identified that the focus of knowledge brokering is not on transferring results of research, but forming the interactive process between the producers (researchers) and users (policy-makers) of knowledge (figure 16) so that they can co-produce realistic and research informed policy options.

**Figure 16: Knowledge brokering interactions**



Source: van Kammen et al, 2006, p. 609

### 2.4.3 The role of SME's in Innovation

It has been noted that creation of new business ventures and innovation in existing small and medium-sized enterprises (SMEs) are critical parts of today's innovation process, and should take a central place in government strategies to promote innovation (OECD, 2010, p. 23). Nowadays, new firms as well as innovating SMEs are best seen as agents of change in the economy, by introducing new products, services and more efficient ways of operation, as they underpin the adaptation of economies and societies to new challenges and are drivers of economic development (ibid). Small and medium-sized enterprises (SMEs) are progressively perceived with a high importance to policymakers (Hoffman et al. 1998). This occurs as most economies are largely composed of SMEs and despite the presence of large firms, most employment is concentrated around them (ibid). In small enterprises however, innovation and technological development is not vital because of its direct benefits in terms of increased output or employment (Roper, 1997).

Roper (1997) acknowledged that the ability of small firms to accomplish the role of Schumpeter as the motivators or facilitators of technological change stems from their compliance and flexibility (Wynarczyk et al. 1993), their closeness to the market, internal reliability and cases the willingness of the governing entrepreneur or senior manager in undertaking possible risks (Rothwell and Zegveld, 1982). In 1984, Rothwell recognised that small firms and especially new small firms appear to be better at adapting to the rapidly changing requirements of an industry, compared with mature and established companies, which often experience great difficulty in adopting an industrial change.

Since SMEs have fewer resources for innovation purposes and fewer technological assets, researchers pay less attention to their innovative nature and management (Acs and Audretsch, 1987). Nonetheless, despite the limitations in resources and assets, SMEs are significant for different types of innovation - both technological and non-technological (ibid; Vossen, 1988). Table 6 summarises the works that have been done within the context of innovation in SMEs, the focus of the studies and the key insights of the investigations:

**Table 6: Studies on SMEs**

Authors	Year	Key Focus	Type of Study	Key Insights
Mosey	2005	How SMEs build a dynamic capability to develop "new-to-market" products	Longitudinal case study	Distinct development processes satisfy the unmet needs of new customers using current technologies with the use of cross-functional teams with an ever-increasing number of pioneering partners can sustain this activity

De Toni and Nassimbeni	2003	Suggested ways of improving new product development within the small and medium enterprises	Multiple case-study analysis and structured and un-structured interviews	Formal language, codified knowledge, and shared standards are requested in order to develop alliances and interactions on enlarged scale
Cagliano and Spina	2002	Comparing the practice-performance links for two types of SMEs such as subcontractors and small manufacturers	MICROSCOP E database - descriptive analysis	SME's implement advanced practices in different areas of management, and to obtain good performance both at the operational and business level
North and Smallbone	2000	How innovation exists in rural SMEs in England	Survey of 330 firms	Only little difference is found in the level of innovation between SMEs in the different areas, as a remote rural location is shown to influence innovation in different aspects of the business in different ways

Humphrey and Schmitz	1995	The importance of clusters and networks for SMEs	Case study firms	Clustering matters in developing countries as assisting groups of enterprises is more cost effective than assistance to individual enterprises
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Source: Compiled by author

The studies mentioned above showed that governments are providing resources as a way of encouraging exporting activities and boosting innovation, as they are regarded as the ultimate drivers of economic growth (Higón and Driffield, 2011). It was shown that the growth of government policies to promote exports, expanded market opportunities for the most productive firms in a particular sector (Bernard and Jensen, 1999). Additionally, it was confirmed that government funding plays an important role in all countries, with national funding having a huge impact (Griffith et al 2006).

The pharmaceutical industry is an excellent example, as SMEs within the sector are likely to expand their size and value from collaborations due to their inherently limited capacities and capabilities (Nooteboom, 1994; Bougrain and Haudeville, 2002; Rogers, 2004; Braun et al, 2012, p. 30). In other words, small and medium sized firms have been always carriers of innovation, collaboration and traders of information and technologies. Table 7 indicates several studies that investigate the importance of SME’s in the context of open innovation, based on a deductive or inductive paradigm.

**Table 7: Studies of Open Innovation in SMEs**

Author(s)	Year	Key Focus	Type of Study	Key Insights
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Christensen, Olesen, and Kjaer	2005	Innovation strategy and management	Qualitative study	SMEs manage open innovation with respect to emerging technologies based on their position within the innovation system and their stage of maturity of the technology.
Lecocq and Demil	2006	Open innovation strategy	Quantitative study	The study finds that the introduction of open system strategy leads to an increased number of new entrants into the industry as they adopt open systems more readily than incumbents.
Henkel	2006	Informal development collaboration (Open source software development)	Quantitative study	It was found that smaller firms are likely to benefit from open source software development as they usually need external development support.

<p>Laursen and Salter</p>	<p>2006</p>	<p>Search strategy for external knowledge</p>	<p>Quantitative study</p>	<p>The study suggests that firms that are open to external sources and search channels are likely to have a higher level of innovative performance. However, over search would result in negative effect on innovative performance</p>
<p>Lichtenthaler</p>	<p>2008a</p>	<p>External technology acquisition and external technology exploitation</p>	<p>Quantitative study</p>	<p>The study found that open innovation was mainly practiced by large firms, as they are not able to rely solely on internal activities due to the diversification of the technology knowledge that they use.</p>

Van de Vrande, De Jong, Vanhaverbeke, and De Rochemont	2009	Technology exploitation and technology exploration	Quantitative study	Medium-sized and large firms were found to embrace open innovation to a larger extent. However, SMEs were increasingly opening their innovation process to cope with lack of internal resources.
Bianchi, Campodall'Orto, Frattini and Vercesi	2010	Outbound open innovation (out-licensing)	Qualitative study	The study provides an overview on a quick and easy-to-use methodology for identification of viable opportunities for licensing out alternative technology applications.
Lee, Park, Yoon, and Park	2010	Technology exploitation and technology exploration	Quantitative and Qualitative studies	The study presents different models of open innovation within SMEs. An intermediate network model and the important role of intermediate organisation in supporting SMEs.
Brunswick and	2011	External innovation	Qualitative	The study enriches the existing

Vanhaverbeke		sources	study	literature on open innovation search in SMEs and provides an insight into the particular nature and value of five different open innovation search strategies.
Higón and Driffield	2011	Exporting and innovation performance	Qualitative study	The study analyses the determinants of the export propensity of UK small and medium-sized enterprises (SMEs) based on the 2004 Annual Small Business Survey.

Adopted from: Brunswicker and Vanhaverbeke, 2011; Higón and Driffield 2011; Parida et al, 2012

As the literature follows a stance towards SMEs, it is important to grasp the opportunity and assess their significance in terms of open innovation application and adoption. The following section provides the conceptual framework of the study that includes SMEs, knowledge brokers and large companies, entities which thus far have not been addressed by the literature. Additionally, the framework will describe how the open innovation concept can be examined within a multi-layered perspective, components of which have not been examined by the literature thus far.

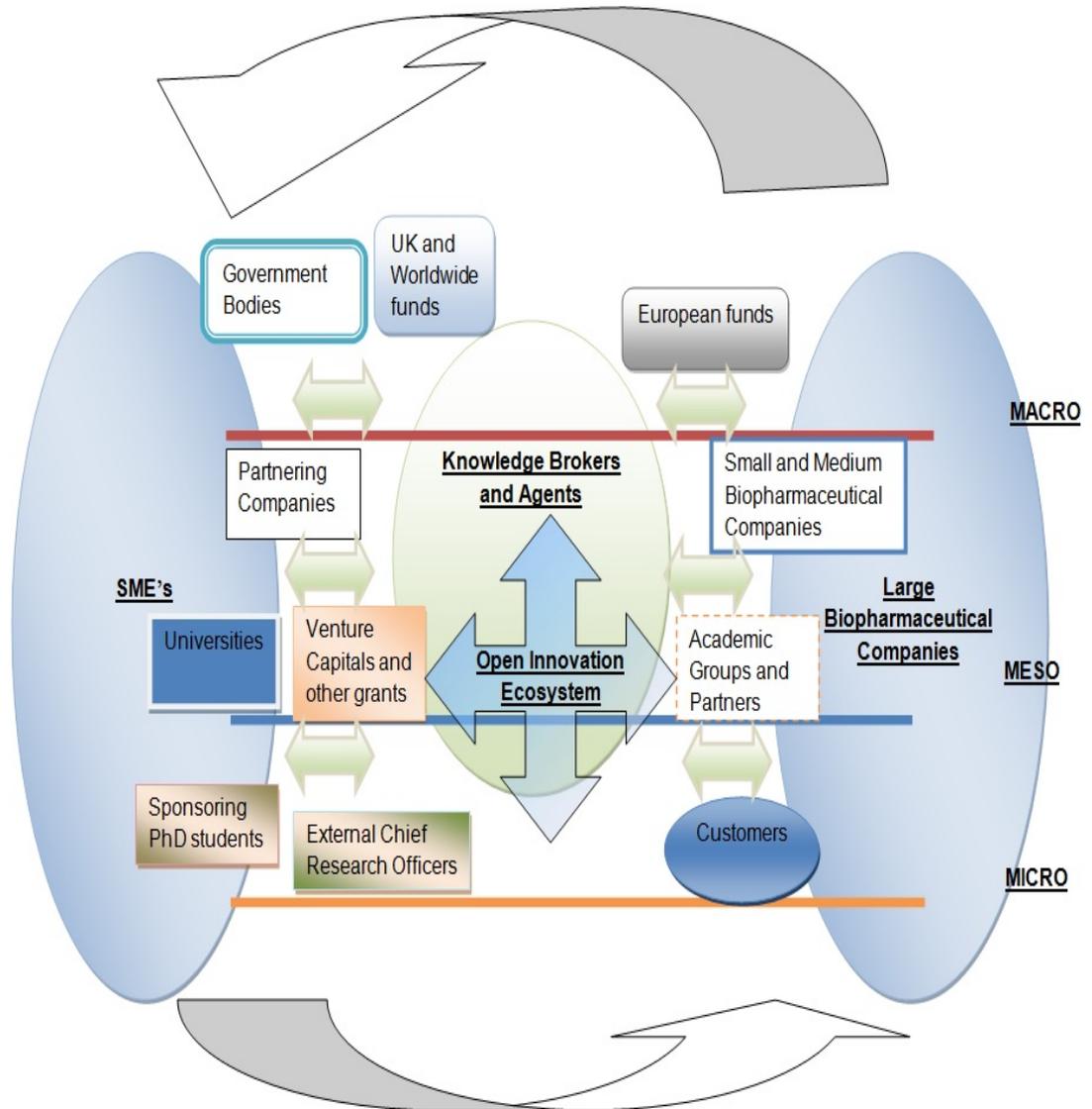
## 2.5 Conceptual framework

To evaluate open innovation, there is a need to develop a framework that will identify and assess the main areas of the study. A conceptual framework is

defined as a visual or written outcome, which “*explains, either graphically or in narrative form, the main objects that need to be studied, the key factors, concepts, or variables, and the presumed relationships among them*” (Miles and Huberman, 1994, p. 18). The conceptual framework is mainly a conception or a model of what the plan of the study is (Maxwell, 2005, p. 33), therefore the framework of the study draws on: the Biopharmaceutical sector, including SMEs, knowledge brokers and large firms. Brokers work as intermediates between SME’s and large companies, so the study will examine their relation to the open innovation model adoption, and their thoughts towards the acceptance of the open concept by the industry.

As a result of the literature review, the framework is formed which will then be supplemented with the findings from the interviews and survey questionnaires. The conceptual framework of the study has been developed after considering the several elements that influence the appearance of innovation as it has been described from the literature. As innovation can be examined in a multi-level, the study adopts Crossan and Apaydin’s (2010) identification in which the dimensions of innovation can be attributed to a firm’s internal characteristics and the conditions in which the firm operates. On this, the study perceives that SMEs, knowledge brokers and large companies operate in such multi-layered conditions, where interactions and associations are central to their daily activities, as shown in figure 17.

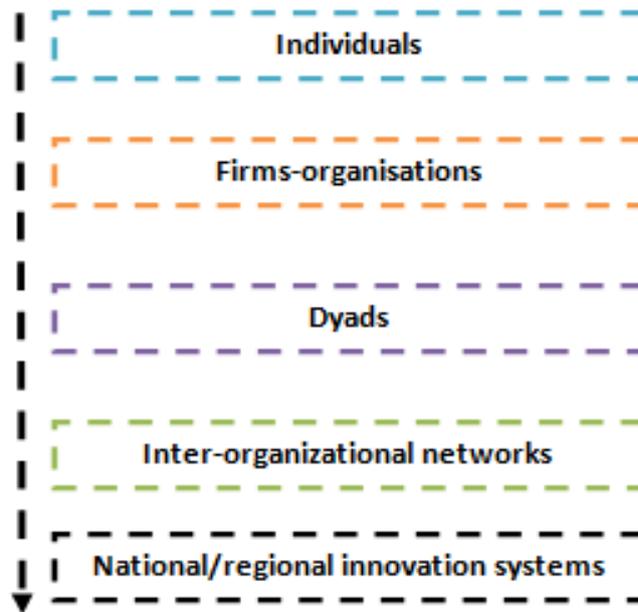
**Figure 17: Conceptual framework of the study**



Source: Developed by the author

The literature suggests that an investigation of the open innovation has to be examined at different levels, through the inclusion of the various elements that create these underlying conditions (Vanhaverbeke and Cloudt 2006):

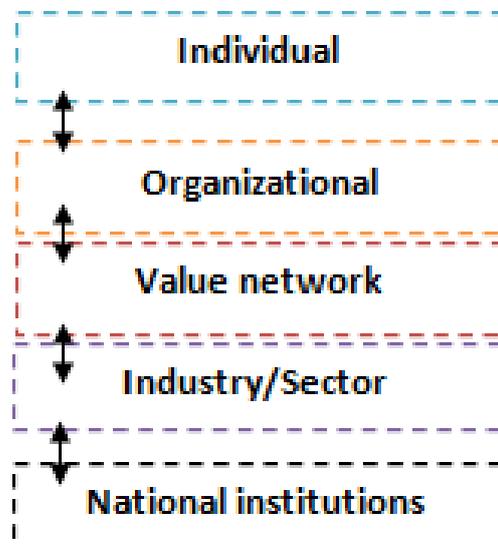
**Figure 18: Levels of open innovation investigation**



Source: Vanhaverbeke and Cloudt, (2006, p. 276)

When using the multi-level approach, the study clarifies the levels of which the framework operates, which according to West et al, (2006) open innovation can be analysed on the following levels:

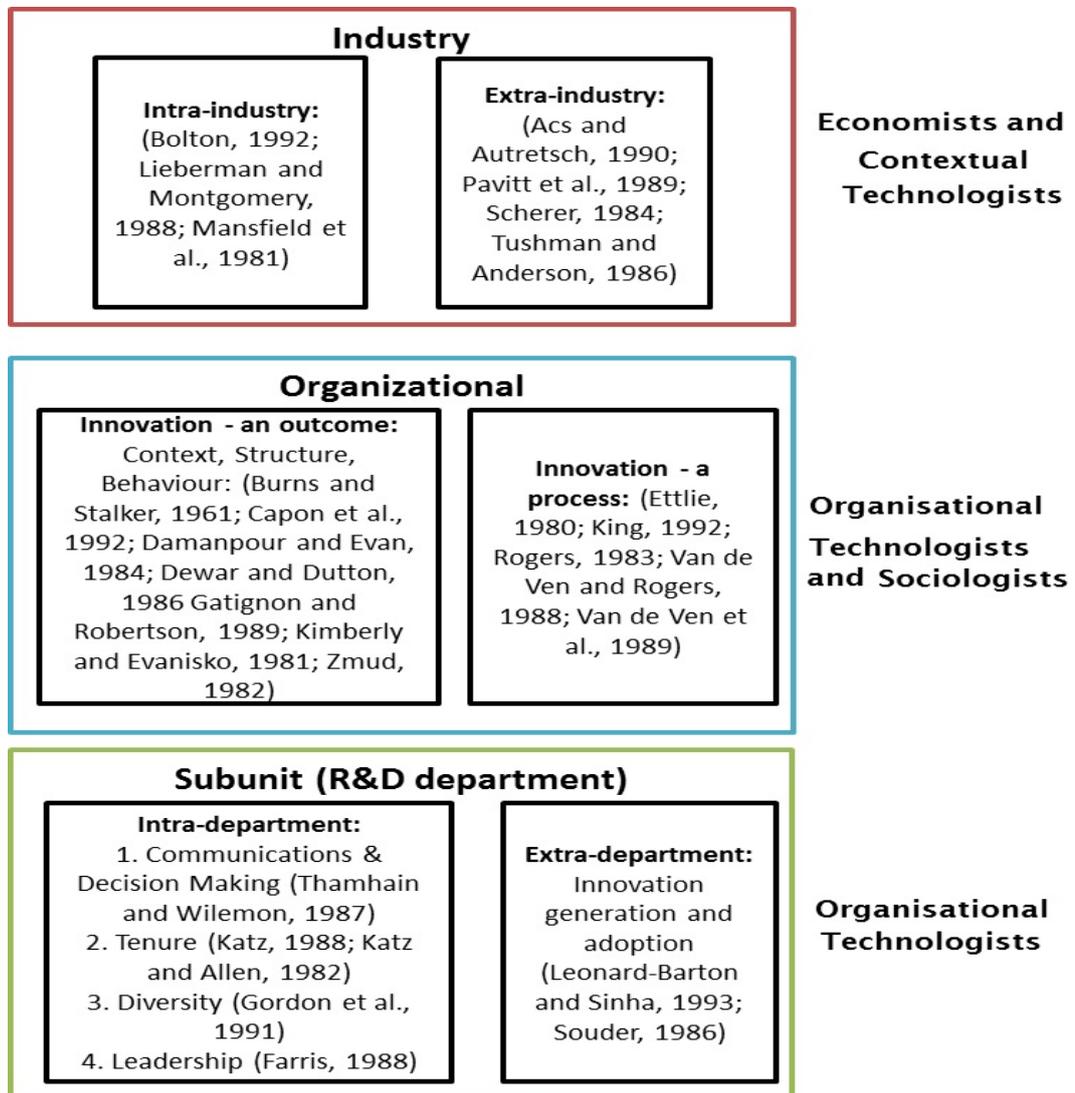
**Figure 19: Levels of analysis of open innovation**



Source: West et al, (2006, p. 287)

In line with the multiple levels of analysis, Gopalakrishnan and Damanpour (1997) stressed the significance of multiple levels of analysis in innovation, namely the industry (macro), organisation (meso) and sub-unit (micro). Through figure 20, the study illustrates the levels and dimensions of innovation and how its multidimensional nature can be structured.

**Figure 20: Dimensions of innovation**



Source: Crossan and Apaydin, 2010, p. 1181

A significant feature in innovation studies is that the multilevel phenomenon of innovation is not only attributed to a firm's internal characteristics but also the framework conditions in which firms operate (Srholec, 2011, p. 1539). This indicates and emphasizes the significance of multiple aspects that effect innovation in firms and organisations. An important characteristic during the

application of innovative techniques and approaches from an organisation is leadership, as it plays an important role at all levels in directing innovation as a process and maintaining its motion until an innovative outcome occurs (Crossan and Apaydin, 2010).

An important characteristic of the multi-level approach is that it distinguishes a number of levels of society in nature and recognises the selective forces that operate at these levels (Kerr and Godfrey-Smith, 2002, p. 478). In general, the micro-meso-macro approach is gaining the interest of many researchers, of whom (Dopfer et al, 2004; Dopfer and Potts, 2004) have registered their interest. The innovation process is regarded as being embedded within a thorough multi-layered structure, then innovations can be defined as long term multi-level transformation processes (Weber et al. 2006). Especially, the micro-meso-macro framework can be used to analyse the innovation systems to aid identification of the spatial, political or industrial location within national innovation systems, local clusters, regional innovation systems or sectorial innovation systems (Kastelle et al, 2012). Similarly, systems of eco-innovation have been analysed at these specific levels as follows (Reid and Miedzinski 2008):

- 1) The micro (product, service, process, company)
- 2) The meso (sector, supply chain, region, product/service system)
- 3) The macro (economy-wide)

On this, several scholars indicate the characteristics of open innovation which can be found in several levels of analysis, such as individuals, firms and organisations, dyads, inter-organisational networks as well as national and regional innovation systems (Huang, 2011; Vanhaverbeke and Cloudt, 2006; West et al, 2006). Most importantly, Chesbrough et al (2006) indicated a multiple level of analysis stresses at three levels:

- 1) Within the firm
- 2) Between firms
- 3) Within the surrounding institutional environment

As innovation is better understood on a multilevel approach (Crossan and Apaydin, 2010), it is imperative to assess the firm within a broader structure to capture its innovative nature. Introducing new models require a close study of the innovation activities of the organisation from multiple levels of analysis (Chesbrough et al, 2006, p. 11). Within the multi-layered framework, open innovation recognises that by leveraging its capabilities and expertise to and from others, an organisation can deliver not only differentiated but also meaningful innovation (Perkins, 2008). What comes out of multi-layered studies is that there is a clear concern for establishing directions through multiple levels that can open the direction for studies in innovation to more theoretical and ontological traditions that have been neglected up until now (Smith et al, 2010, p. 436).

Analysis on the individual level will include the organisational (micro), the value network; the industry/sector will be analysed as one (meso) and the national institutions separately (macro). The multi-layered approach can evaluate the relations on a micro level (with various individuals), the relations with other firms and institutions on a meso level and the relations with government bodies for policy regulation purposes on a macro level (Hage et al 2007). Multi-layered approaches have been stressed to deliver a complex and rigorous framework, which delivers capabilities for the researcher to capture the complexity of real organisational developments (Klein and Kozlowski, 2000, p. 211). What is important is that the particular analysis can be described by a multi-level approach, which recognises how the transition of a business model aligns at multiple levels, as described below:

- | **Micro** - Interactions with various individuals (internally and externally)
- | **Meso** - Relation with companies, other firms or institutions (externally)
- ↓ **Macro** - Interaction with regulatory bodies at a national and international level (externally)

Table 8 describes the consideration of a multi-layered approach for the study as follows:

**Table 8: Elaboration of the multi-levels approach**

<b>Analytical Levels</b>	<b>Translation to the Study</b>
Micro (Individual level)	Individuals: CEOs/Directors (SMEs and large Biopharmaceutical ); Key individuals (Academics in Universities, Brokers, External Associates)/Actions and approaches in innovation
Meso (Firm level)	Firms and Organisations (SMEs and large Biopharmaceutical firms/Academic institutions/Contract research organisations ) Actions and collaborative approaches in innovation through interactions among entities
Macro (Firm and Contextual level)	Regulatory bodies, Government, EU and Global funds; Settings and relations that influence national and international institutions and bodies, interactions between firms and institutions for mutual understanding

Source: developed by the author

The principal objective of the study is to examine the adoption of open innovation in the Biopharmaceutical industry, with the investigation of SMEs, large companies and knowledge brokers. In doing so, the study can identify the opportunities and barriers it creates and provide further recommendations for firms in the Biopharmaceutical sector. With critical realism, the study uses retroductive reasoning to identify the actors-agents (individuals) responsible for the adoption of a business model and evaluates how their decisions (causal powers) and necessary relations affect the implementation of an open business model in an individual - industry - policy relation context.

## 2.6 Key observations

Through the review of the literature, several key observations arose concerning the concept of open innovation as follows:

1. Most studies around the notion of open innovation have been focused on large firms, multi-national corporations and high tech industries, and

to date, most studies around open innovation are exploratory and descriptive in nature (eg. Belderbos et al, 2014; Bianchi et al, 2011; Parida et al, 2012). This study delivers an explanatory approach in indicating and explaining how and why open innovation practices occur; this shows the concept is being accepted and utilised in management literature.

2. To date, few studies have been critical to the open innovation concept, as early publications have been characterised by an appeal towards the topic without explaining its application beyond the contexts of IBM and P&G (Fredberg, Elmquist and Ollila, 2008). As the majority of studies in open innovation thus far have focused around high-tech examples (Chesbrough, 2003a; Laursen and Salter, 2005), not much focus has been given to how open innovation operates in other sectors such as the Biopharmaceutical sector, despite it being considered one of the largest contributors to the UK economy<sup>7</sup>.
3. Given that SMEs have not received much attention studies in open innovation (Colombo et al, 2014; Lee et al, 2010; Spithoven et al, 2013), the present study grasps the opportunity to explore the opportunities and barriers open innovation offers to SMEs in this context. As SMEs represent the vast majority of employees and claim to enhance competition and entrepreneurship<sup>8</sup>, this focus is critical for a deeper understanding of the dynamic functioning of the Biopharmaceutical sector as a whole.
4. The contribution of the pharmaceutical sector to the UK balance of trade is among the greatest of 9 major industrial sectors, with a spending of 28.4% of the UK total R&D expenditure in 2009, the highest of all the sectors in the UK. In 2011 the average daily research & development investment in pharmaceuticals reached £13.7million<sup>9</sup>, the largest investment in medicine development in Europe. As SME's account for almost 90% of the total UK life science companies, this study will

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<sup>7</sup> ABPI - The pharmaceutical industry and market in the UK

<sup>8</sup> Strength and opportunity 2012

<sup>9</sup> Strength and opportunity 2011

produce new knowledge for firms, policymakers and educators by revealing their attitude towards new methods and innovative techniques.

5. Due to increasing costs, Biopharmaceutical firms find it hard to continue with their internal R&D (Hara, 2003). Knowledge brokers and agents can play an important role as intermediates by influencing and facilitating several collaborative projects (Hargadon, 1998). With regards to the study, knowledge brokers can be used as an important source of information concerning the directions and attitude not only the firms but the sector as a whole.
6. There is a distinct lack of empirical work in the contexts of the individual, sectorial and governance levels (micro-meso-macro). The missing elements include the role of individuals, the processes of exchange of information and ideas, and the interactions with governing bodies and global funds. It is evident that not much work has been done regarding the expansion of knowledge of the open innovation process, as there is limited theoretical development in the sector that recognises multiple levels of analysis, wide range of actors and influence (see Vanhaverbeke and Cloudt, 2006 and West et al, 2006). The use of critical realism that identifies the causal mechanisms and powers that assist in the creation of open innovation activities, may generate useful new knowledge; hence its adoption here offers deeper explanations regarding the causes of open innovation adoption in the Biopharmaceutical industry. As open innovation is considered a business model (Chesbrough, 2003a), its adoption goes through the traditional channels of approval of the firm's senior management (Finkelstein et al, 2009, p. 101). Therefore critical realism can trace the causal influences that create an event such as the adoption of a new direction or the prolongation of the existing, which is explored in detail in section 3.5.

## **2.7 Research Objectives and Questions**

A number of enquiries have arisen from reviewing the literature regarding the implementation of the open innovation concept within the Biopharmaceutical industry. The study draws upon existing literature to develop the main objectives of the embrace of open business models, as evidence shows their

success in other industries (Chesbrough, 2003a; 2006; 2007; Pontiskoski and Asakawa, 2009; Hunter and Stephens, 2010).

As the Biopharmaceutical sector combines and exchanges resource influences in value creation by developing new products through innovations, it has been selected for the study based on its dynamic capabilities and innovative nature (Hara, 2003; Tsai and Ghoshal, 1998). Additionally, little attention has been placed on the critical effects of open innovation in sectors beyond high tech and multinational corporations (Bigliardi et al, 2012; Spithoven et al, 2010; Van De Vrande et al, 2009), with an absence of critical realist views and interpretations.

The overall aim of the research is to generate an understanding of the opportunities and barriers open innovation provides in the UK Biopharmaceutical industry. In doing so, the study investigates the perspective of SME's, knowledge brokers and large firms, by identifying why and how open innovation practices occur. Due to this, the study will employ a critical realist view on a micro-meso-macro analysis, looking into a multilevel layer investigation of the open innovation concept. Table 9 shows the objectives and the questions of this research.

**Table 9: Open Innovation in the Biotech and Pharmaceutical Industry**

Objectives	Questions
<p><b>Objective 1:</b> Explore the processes and relationship of and between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies</p>	<p><b>Question 1:</b> Do SMEs use any novel and innovative business models throughout the processes of their innovation progress?</p>
	<p><b>Question 2:</b> Is open innovation paradigm a way forward for SMEs and large Biopharmaceutical firms?</p>
	<p><b>Question 3:</b> To what extent does open innovation progress in large Biopharmaceutical companies?</p>

	<p><b>Question 4:</b> Is open innovation considered as a long term strategy for large Biopharmaceuticals?</p>
<p><b>Objective 2:</b> Demonstrate the significance of open innovation strategies in terms of its fundamental properties and aspects, such as in/out source, IP in/out source and open collaborations.</p>	<p><b>Question 5:</b> In terms of Research and Development, do SMEs out-source or in-source techniques or ideas through effective collaborations with various individuals or institutions?</p>
	<p><b>Question 6:</b> Intellectual Property is seen as an important factor of open innovation processes, do such activities exist in SME's and what is their attitude towards IP protection and sharing?</p>
	<p><b>Question 7:</b> Do internal boundaries in SMEs and large firms tight in response to open innovation strategies?</p>
	<p><b>Question 8:</b> What is the role of Knowledge Brokers and Agents between SME's and Large firms during the creation of necessary and collaborative forms?</p>
	<p><b>Question 9:</b> What is the approach of SMEs' and Large Companies towards open innovation model in terms of profit and technological expansion?</p>
<p><b>Objective 3:</b> Explain in a critical lens the structure in which open innovation processes are</p>	<p><b>Question 10:</b> What examples exist to support that open innovation is a way forward for Biopharmaceutical companies?</p> <p><b>Question 11:</b> How Biopharmaceutical firms interact with various individuals, groups, firms and organisations (micro-meso-macro)</p>

exercised within the Biopharmaceutical sector	<b>Question 12:</b> How Biopharmaceuticals firms communicate and share information and technologies during their research and development activities
	<b>Question 13:</b> What are the circumstances (on a firm and context related level) that influence innovation and consequently open innovation amongst firms in the sector?
	<b>Question 14:</b> How much do the environment and aspects of open innovation influence firms in the Biopharmaceutical sector?

Source: developed by the author

The central aim of this study is to provide an insight into the open innovation concept, and an in-depth understanding regarding the opportunities and barriers it creates for Biopharmaceutical companies. For that reason, the study provides:

- A complete and broad emphasis on open innovation within the context of an innovative sector (Biopharmaceutical).
- As a critical view (explaining events by identifying and explaining the underlying mechanisms) does not exist, the study will provide a solid understanding of how and why open strategies occur.
- The use of a multi-layered architecture framework will stress the role of firms and their perspective, but more importantly the role of individuals within a firm and sectorial elements and structures, which have been so far ignored by the research in open innovation.

With the utilisation of critical realism as a paradigmatic lens, the study will trace the people who through their causal powers and mechanisms create the necessary conditions, which are responsible for the facilitation and production of open innovation practices. This includes the events that affect the strategy of SME's and large Biopharmaceutical firms. The use of critical realism will

trace the casual and impulsive mechanisms of individuals, by exploring the fundamental cause of observed events to explain their development.

An essential principle in critical realism is that reality is stratified (Real-Actual-Empirical) and non-linear, consisting not only of events but objects, including structures, which have powers and liabilities capable of generating events (Sayer 1992). In the following chapter 3, the paradigmatic considerations of the study will be set, to explain and demonstrate the influence specific paradigms have for this study.

## 3. Paradigmatic underpinnings

### 3.1 Introduction

The purpose of this chapter is to establish the ontological and epistemological themes of the study. The approach used to guide the research will be assessed, as the research strategy and tools will accomplish the objectives of the study. Several perceptions are emphasised as paradigms of choice in innovation research, mainly positivism (quantitative - deductive) and constructivism (qualitative - inductive), with the argument made in favour of critical realism (post-positivism - retroductive). This includes a discussion of the strengths and weaknesses of each paradigm, and the focus on the evolution of critical realism in management research, and its implication in innovation studies. The elements of critical realism, such as retroduction, stratified reality, causal mechanisms and powers will be proposed to indicate its appropriate use for the study.

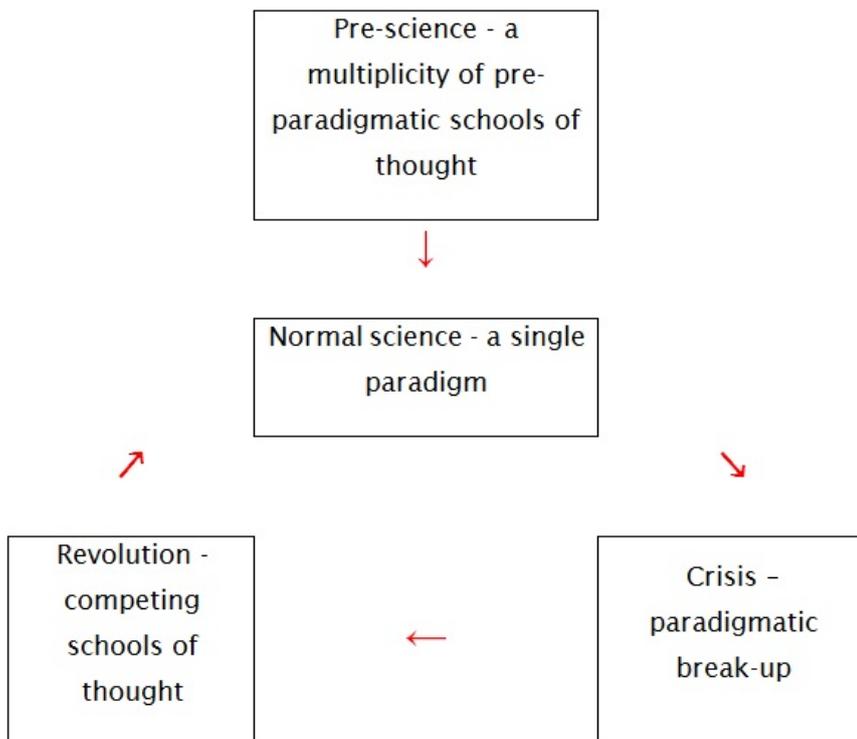
### 3.2 Research Paradigms

In any research, there is a necessity to explain and clarify the framework upon which the study will be based, as the nature of social research involves the use of a theoretical lens that each study has to follow (Creswell, 2007, p. 16). This denotes that a paradigm influence what should be studied, how a research should be done, and how results should be interpreted (Bryman, 1988, p. 4). Burrell and Morgan (1979, p. 23) suggested four paradigms in social science as *“metatheoretical assumptions, which underwrite the frame of reference, mode of theorising and method of operation of the social theorists who operate within them”*, as all theories of the social order are based upon a philosophy of science. In deciding upon a paradigm, the researcher faces the principal qualitative and quantitative concepts that can easily lead to a struggle.

‘Paradigm’ was introduced by Thomas Kuhn (1962) as *“the practices that define a scientific discipline at a certain point in time”*, such as a pattern, model or a plan (Johnson and Duberley, 2000, p. 68). This implies that a paradigm is more general than a theory but more focused than a world view

(Bruce and Yearley 2006, p. 224). A paradigm is set to present a series of assumptions concerning reality (ontology), knowledge of that reality (epistemology) and the particular ways of knowing that reality (methodology) (Guba, 1990). This will consequently form our recognition of how the world exists around us by demonstrating how data is collected, analysed and presented. Figure 21 describes the approach of the development of a paradigm and how that changes according to Kuhn (1962).

**Figure 21: Kuhn's view of scientific development**



Adopted from Johnson and Duberley (2000, p. 69)

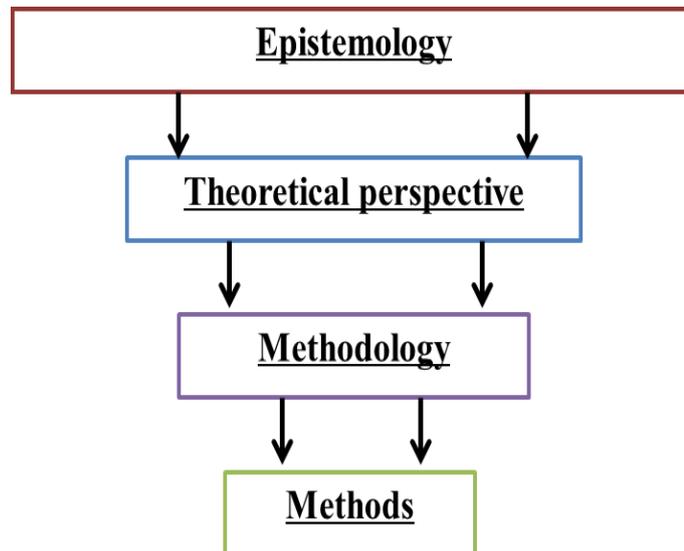
Paradigms can assist the researcher in developing an understanding of how the world is perceived by the people around us, as it stands for the entire composition of beliefs, values and techniques that are shared by the members of a community (Kuhn, 1970). Kant (1983, p. 12) debated that the aim of philosophy is to explain how particular trends of thought have objective validity, which can provide conditions for the possibility of knowledge of all objects. It has also been debated that the questions of paradigm precede the questions of method as it is the world view that guides the investigation, not only in method preferences but in ontological and epistemological

fundamental methods (Guba and Lincoln 1994, p. 105). The following section 3.3 delivers a detailed description the various paradigms choice in social research.

### 3.3 Paradigms in social science

Central to any research are the fundamental concerns regarding the nature of the study, as the researchers theoretical lens is advocated to perform an important role in the choice of methods. The underlying belief system of the researcher (ontological assumptions) largely defines the choice of a method (methodology) (Dobson, 2002). This can be validated from figure 22, which identifies the actions of choice that define the data collection techniques and the systems of analysis (Crotty, 1998). Specifically, the research philosophy determines the approaches and strategies, which will lead to the methods to be employed for data collection.

**Figure 22: Research framework based on epistemology**



Source: Crotty, 1998, p. 4

Through a comprehensive philosophical framework, Burrell and Morgan (1979) provided explanations of the subjective and objective dimensions of social science. They suggest that all theories of organisation are based upon a philosophy of science and a theory of society. Therefore social scientists approach their topic through either explicit or implicit assumptions about the

nature of the social world and the way in which it can be investigated (ibid, p. 1). These assumptions are of an ontological and epistemological nature, which are associated with human nature and have direct implications of a methodological nature.

For almost a century the quantitative and qualitative research paradigms have been developed by scholars, with arguments and discussions being based on the fitness of each approach (Johnson and Onwuegbuzie, 2004, p. 14). Quantitative dogmatists (Ayer, 1959; Maxwell and Delaney, 2004; Popper, 1959; Schrag, 1992) formulate assumptions that are consistent with what is commonly called a positivist philosophy. In this case, social observations should be treated as entities in much the same way that physical scientists treat physical phenomena.

Alternatively, qualitative dogmatists (Guba and Lincoln, 1989; Lincoln and Guba, 2000; Schwandt, 2000; Smith, 1983, 1984), known as constructivists and interpretivists, reject positivism. They debated that explanations are generated inductively from the data, as the knower and known cannot be separated because the knower is the only source of reality (Guba, 1990). Fasnacht (2009, p. 63) argued that management research is a non-reductionism discipline that combines positivism and interpretive paradigms because it engages academic theories as well as business practices and so requires both quantitative and qualitative methods. The following section 3.3.1 explains the different approaches of positivism and constructivism in social research and how they are applied in management and innovation research.

### **3.3.1 Positivism and Constructionism as social paradigms**

Positivism is described as recognition of understanding the principles that dictate the performance of a real world, based on the forming of theories (induction) from data and testing it against the theories (deduction) (Popper, 1976). On this, positivism assumptions can provide the overall cause that underpins most theory of research in the social sciences, as it refers to a set of epistemological perspectives and philosophies of science. They state that the scientific method is the best approach in revealing the processes by which both physical and human events can occur (Johnson and Duberley 2000).

In management research, the aim of positivism should be to identify causal explanations and fundamental laws that explain regularities in human social behaviour to generate laws which govern the ways in which organisations operate. Positivists believe that reality is stable and can be observed and described from an objective viewpoint (Levin, 1988). Furthermore, Alavi and Carlson (1992) debated that all the empirical studies were positivist in approach. Orlikowski and Baroudi (1991, p. 5) discussed how studies classified as positivist were evidence of formal propositions, using quantifiable measures of variables, hypotheses testing and were drawing inferences about a phenomenon from the sample to a stated population, with exceptions being the 'descriptive' studies. Saunders et al. (2009) emphasised that a positivistic approach is based on quantifiable observations that lend themselves to statistical analysis.

On the other hand, constructionism compared to positivism, is considered an ontological position that places an emphasis on social phenomenon and their values being constantly accomplished through social actors and are given meaning by people (referred to as 'socially constructed') (Saunders et al. 2009, p. 111). Constructionism is considered an ontological position that places an emphasis on social phenomenon and their values being constantly accomplished through social actors (ibid). Social constructionism stems from the assessment that reality is not objective and exterior but is socially constructed and given meaning by people (Easterby-Smith et al. 2002). They are conscious, purposive actors with ideas about their world and attach significance to what is going on around them (Robson, 2002). Constructionism thus traces how evidently natural occurrences are constructed through a history of human actions and interactions (Turner 2006, p. 569). The deductive approach to research has become synonymous with positivism, whilst inductive approach with social constructionism (Gill and Johnson, 2002).

Easterby-Smith et al. (2002) contrast the implications of positivism and social constructionism as follows:

**Table 10: Implications of positivism and social constructionism**

	Positivism	Social Constructionism
The Observer	Must be independent	Is part of what is being observed
Human Interest	Should be irrelevant	Are the main drivers of the science
Explanations	Must demonstrate causality	Aim to increase general understanding of the situation
Progression of Research	Hypotheses and deduction	Gathering rich data from which ideas are induced
Concepts	Need to be operationalised so that they can be measured	Should incorporate stake holder perspectives
Units of Analysis	Should be reduced to the simplest terms	May include the complexity of 'whole' situation
Method of Generalisation	Statistical probability	Theoretical abstraction
Sampling Requirements	Large numbers selected randomly	Small numbers of cases chosen for specific reasons

Adopted by: Easterby-Smith et al. (2002)

With regard to innovation research, most studies are based on a positivist or a non-positivist paradigm, thus open innovation research utilises equivalent approaches. Open innovation research is surrounded by several studies that have been conducted with the application of Grounded theory using qualitative methods and other quantitative techniques. Easterby-Smith et al (2002, p. 28) focused their discussion on two contrasting views of how social science research must be conducted, either with a quantitative (Positivism) or qualitative approach (Constructionism). On the one hand positivism claims that

the world exists externally and its properties should be measured through objective methods, whereas on the other hand social constructionist assessment is based on the fact that reality is not objective and exterior, but that it is socially constructed and is set significance by people (ibid). Section 3.4 presents the studies that have been carried regarding the open innovation concept, highlighting the use of critical realism as a paradigm of choice. It describes the use of critical realism and subsequently retrodution methods in explaining the adoption of open innovation strategies within the UK Biopharmaceutical industry.

### 3.4 Studies in open innovation

Open innovation has been characterised as a business model (Chesbrough and Garman 2009) that can be effective in creating and capturing value. This is due to the fact that it allows intellectual property, ideas and people to flow freely both into and out of an organisation (ibid). Several studies have approached open innovation based on Positivism, with most noticeably Laursen and Salter (2006) and Lichtenthaler (2008a). More precisely, Lichtenthaler (2008a), through a cluster analysis, explored the extent of external technology exploitation. Laursen and Salter (2006), however, explore the innovation process inside firms using regression analysis (Tobit model). Moreover, Dittrich and Duysters, (2007) with the use of quantitative approaches, identified that Nokia utilises an open innovation strategy on their new product development. Table 11 illustrates the various approaches used in open innovation studies.

**Table 11: Nature of studies in open innovation**

Qualitative studies	Quantitative studies
Herzog, 2008	Laursen and Salter, 2006
Reinhardt et al. 2010	Henkel, 2006
Wang et al. 2011	Lichtenthaler and Ernst, 2008
West and Gallagher, 2006	Van de Vrande et al. 2009
Westergren and Holmström, 2012	

Compiled by the author

In open innovation many of the studies are theoretical and descriptive in nature utilising qualitative methods to support their argument, for example

Herzog (2008) and West and Gallagher (2006). At the same time, several studies follow a positivistic paradigm, most noticeably Laursen and Salter, (2006) who identified through a quantitative investigation that firms who open to external sources and search channels are likely to have a greater level of innovative performance. Moreover, Lichtenthaler and Ernst (2008) used the paradigm on a benchmarking study that evaluated the external technological commercialisation of large firms.

Various studies on the other hand, such as Dodgson et al. (2006) utilised an inductive paradigm to investigate open innovation in Procter and Gamble's program the Connect and Develop. This shows that some social constructivists developed their studies with the application of grounded theory (Herzog 2008; West and Gallagher 2006). This allowed them to investigate the behavioural reasons responsible for innovation growth (Herzog 2008, p. 209) and on the challenges of open innovation (West and Gallagher 2006). In addition, O'Connor (2006, p. 79) 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. From the study, O'Connor (2006) identified that open innovation, if managed in a balanced way with internal capability development, can speed up radical innovation. Furthermore, Van de Vrande et al. (2009, p. 436) supported the argument and pointed out that studies in open innovation are largely based on qualitative research approaches.

Although positivism and constructivism can deliver explanations of events and circumstances, the use of critical realism (post-positivism) will identify how particular objects (individuals) through their influence (causal powers) and connections (necessary and dependent relations) create certain events (strategic decisions). The objective of the study is to evaluate open innovation in terms of opportunities and barriers on an explanatory lens with qualitative methods to systematically develop and test causal explanations (Maxwell and Mittapalli, 2008, p. 324). To this end, the use of critical realism will assist by viewing the world as stratification where *real* actors-individuals, through their *actions* create the *empirical*, which can be accessed and observed via retroductive explanations (Bhaskar 1978). As open innovation has been stressed to be a strategic decision (Chesbrough and Appleyard, 2007), critical realism can assist in identifying from individuals within the Biopharmaceutical

sector that are responsible for the facilitation of strategic decisions, why and how such strategies occur. The following section 3.5 states the argument of critical realism, a theory introduced by Bhaskar (1977).

### 3.5 Critical realism as a paradigm of choice

It is easy to fall into the trap of thinking that one research philosophy is 'better' than another (Saunders et al. 2009, p. 108). It has been distinguished that positivism assesses scientific knowledge as the product of rationality, whereas scientific knowledge must be free of metaphysics, based on pure observation that departs from the interests, values, purposes, and psychological plans of individuals (Howe, 1988, p. 13). In addition, anything that deserves the name 'knowledge', including social science, must measure up to these standards (ibid). Rao and Perry (2007) identified the foundations of scientific paradigms (table 12) from an ontological, epistemological and methodological perception. For this research, the aim is the identification of real strategic events which are accessible through direct observations. This is the point in which positivists and constructivist constraint the meaning of observable events through actual experiences.

**Table 12: Scientific paradigms**

Element	Paradigm		
	Positivism	Constructivism	Realism
Ontology	Reality is real and apprehensible	Multiple local and specific 'constructed' realities	Reality is 'real' but only imperfectly and probabilistically apprehensible; therefore triangulation from many sources is required in order to know it

Epistemology	Findings true; researcher is objective by viewing reality through a 'one way mirror'	Created findings; researcher is a 'passionate participant' within the world being investigated	Findings probably true; researcher is value-aware and needs to triangulate any perceptions he/she is collecting
Common methodologies	Mostly concerned with a testing of theory. Thus, quantitative methods used such as survey, experiments, and verification of hypotheses	In-depth unstructured interviews, participant observation, action research, and grounded theory research.	Mainly qualitative methods such as case studies and convergent interviews

Source: Rao and Perry 2007, p. 128

Realism is a branch of epistemology that is similar to positivism in that it assumes a scientific approach to the development of knowledge (Saunders et al. 2009). Burrell and Morgan (1979, p. 4) argued that realism suggests that “the social world external to individual perception is a real world made up of hard tangible and relatively immutable structures. Whether or not we label and perceive these structures, the realists maintain, they still exist as empirical entities”. Table 13 illustrates the main components of various paradigms and the appropriateness of critical realism as a paradigm of choice.

**Table 13: Positivism, Critical realism and Constructivism Approach**

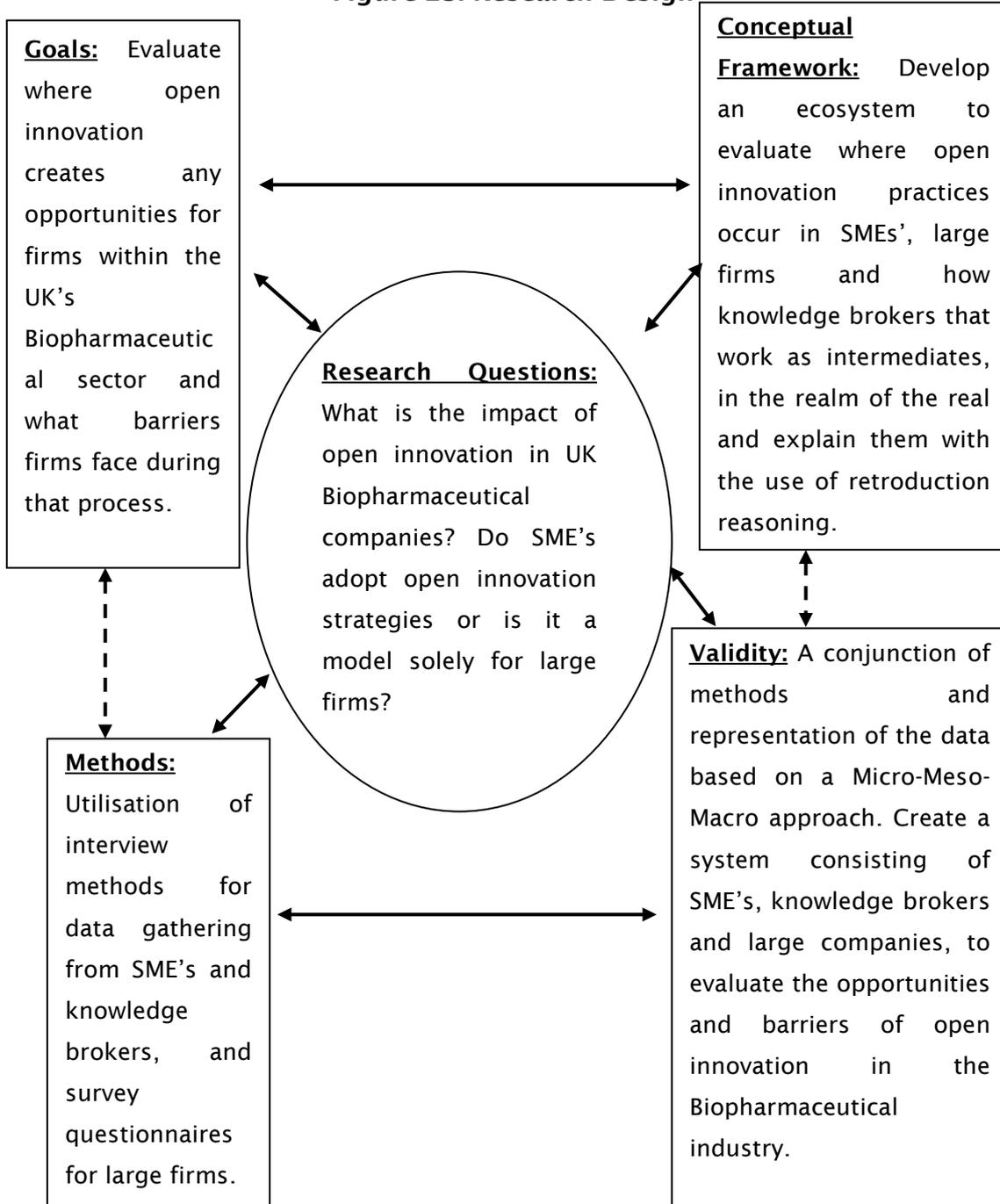
	Positivism	Critical Realism	Constructivism
Ontology	Single objective reality	Domains of real, actual and empirical	Multiple constructed realities

Epistemology	Knower and knowledge are independent	Knower inseparable from transitive dimension of knowledge	Knower and knowledge inseparable
Axiology	Inquiry is value-free	Inquiry is value-laden, but not value-bound	Inquiry is value-bound
Causation	Detectable through observation of event regularities	Causation unrelated to event regularity, but explained by underlying causal mechanisms and how they produce observable events	Impossible to distinguish cause and effect
Generalisation	Time and context-free generalisations from event observation possible	Generalisation from underlying causal mechanisms more reliable than from event observation	Time and context-free generalisations impossible
Primary mode of inference	Deduction	Retroduction	Induction

Source: Courvisanos and Mackenzie, 2011; Tashakkori and Teddlie, 1998

Bhaskar's (1978) critical realism perceives social structures as ontologically real entities. This means that strategic and business relations can be considered ontologically real entities or objects, which can have emergent powers that can cause events under specific conditions. Social structures, unlike natural structures, do not exist independently of the agents conceptions (causal powers of people) of what they are doing in their activity (Bhaskar 1979, p. 38), as the results of social scientific research have the potential to influence the very objects of the study (Archer et al. 1998). Therefore, in this sense strategic decisions can be viewed as social structures that can change over time, for example when a firm alters its strategy towards a different direction. Figure 23 explains the research's design that drive the formation of the objectives, the choice of methodologies and methods, which finally addresses the different sets of subjects that are essential for the consistency of a study (Bickman and Rog, 2009).

Figure 23: Research Design



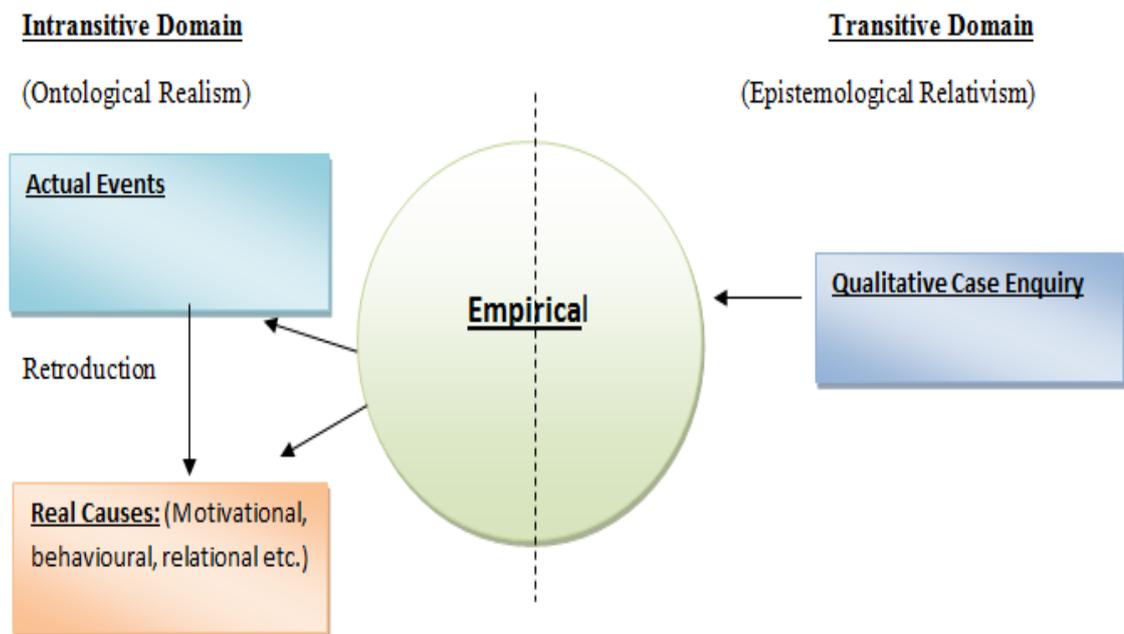
Adopted by Maxwell 2005, p. 9

The design of the research requires prior to the development of the research questions, the creation of a set of goals that will deliver the research methods and which goals are associated to the conceptual framework or the research ecosystem, in which the study will be based to deliver explanations concerning the research goals and all together are responsible for the creation of the research questions (see figure 23). Realism declares both ontological and

epistemological considerations (Bhaskar, 1975), thus in an ontological sense, critical realism as a philosophy retains the idea that there is an existing metaphysical reality, independent of human observation and knowledge. On the other hand, with regard to epistemology, the particular reality is capable of being captured through the practices of abduction and retrodution (ibid).

In relation to the study, the use of retroductive reasoning, which is a mode of inference, the study captures the manner of interpretation in which events are clarified by identifying and categorising mechanisms which are capable of producing them (Sayer, 1992, p. 107). Lawson (2003, p. 80) contended that causal explanation with the use of retroductive reasoning does not require that only the consideration of individual explanatory accounts. On the contrary, retroductive reasoning places no restriction on the sort of explanatory conception that may be uncovered. Downward and Mearman (2007) demonstrated how retrodution can lead from the empirical domain to actual events, and the identification of the real causation of a phenomenon, which is consistent with Lawson’s (2003) notion of explanatory method. The following figure 24 shows how retrodution can lead to the identification of the real causes of an event.

**Figure 24: Intransitive and Transitive Domain**



Source: Downward and Mearman (2007, p. 93)

To organise the concept of the research, the ontological and epistemological considerations reveal the important areas that influence the composition of the research (Sayer, 1992). Ontological considerations provide principal questions on ‘**what can be said to exist?**’ by relating them to ‘*what is open innovation?*’ Epistemological considerations of ‘**how do we know what we know?**’ can be related to “*how open innovation as a strategy can be adopted by firms?*” (ibid). In social science, the paradigms define the significance of individual experience, which can determine the meaning of the research (Krauss, 2005). Paradigms provide the theoretical framework for seeing and making sense of the social world, therefore to be located in a particular paradigm is to view the world in a particular way (Burrell and Morgan 1979, p. 24). The following section describes the paradigmatic influence of critical realism to the research.

### 3.5.1 Critical realism application in the Biopharmaceutical Sector

Pharmaceuticals play an important role for the continuation of life, which makes this industry indispensable. They not only lifesaving lives but are also major contributors to the improvement of the quality of our life (Hara, 2003, p. 1). The pharmaceutical industry is significant not only in terms of product development and pricing, but also in prompting the levels of drug exploitation as a result of marketing and information distribution (Mossialos et al. 2004, p. xviii). At the same time, the biotechnological industry takes novel life science discoveries or technologies and turns them into products. It is one of the highest-profile science-based industries, with billions in R&D investment worldwide (Bains, 2008). As they belong to one of the worlds’ most research-intensive industries, Biopharmaceuticals generate an on-going steam of new products important for the national and global healthcare (Danzon, 1999). In addition, Danzon (1999, pp. 1055 - 1056) identified several features of the pharmaceutical industry that are becoming the central interest in the field of law and economics.

- I. The high rate of R&D, methodological change and importance of patent protection, increases the importance of positive and normative demands related to structure, prices, profits and public policy.

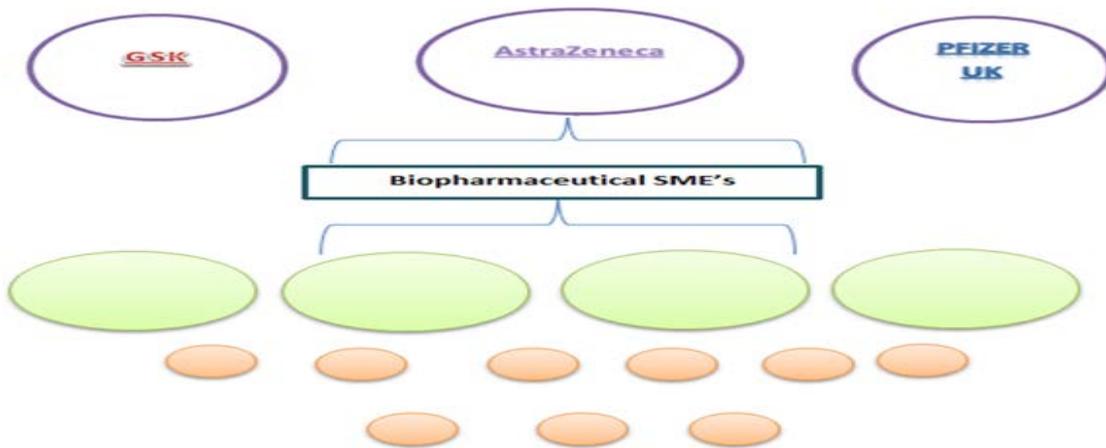
- II. The industry is heavily regulated in all major functions as early regulatory requirements focused on safety and efficacy of a new novelty drug.
- III. Major drugs are global products and the cost of the associated R&D are global joint costs, which creates incentives for national free-rider strategies, while socially optimal policies should consider cross-national spill overs and optimal price differentials.

It is important to mention that the research intensiveness and its competitiveness of the pharmaceutical industry depend on continuous inventions and innovations (Kofinas and Saur-Amaral, 2008, p. 257). This provides a massive motivation for the study, as the characteristics of the Biopharmaceutical industry are formulated through social interactions of entities such as individuals, who apply their causal powers to evaluate a situation or an event. For instance the patent protection, which has a direct effect on the firms' survival, is considered as an interaction between individuals (CEO - scientists) whom have emergent powers that craft the particular patent. The idea that senior managers in firms play a significant role in setting the strategy of a firm has been emphasised in the literature over several decades by Andrews (1971) in corporate strategy and Selznick (1957) in the formation of leadership. Additionally, Virany et al. in 1992 and Virany and Tushman in 1986 stressed the importance of decisions made by top management and executives in corporate success, as senior management teams play an important role in shaping a firm's response (Kaplan et al. 2003).

Several studies identified the significance the Biopharmaceutical firms in the expansion of the global industrial research and development. For example Powell et al. (1996) stressed that biotechnology provides enhanced research productivity with less risk, more speed and with potentially higher rewards (Weisbach and Moos 1995). The process of drug discovery has been regarded as a linear model of technological change (Hara, 2003). This suggests that it starts with scientific research, progresses through technological development and production, and ends with consumption, a notion stressed by Rothwell (1994) in the development of innovation methods.

Nowadays, big pharmaceutical firms have been searching in small biotechnology companies new drug candidates and new techniques, in a way of seeking for innovation, such as searching for partners that are more or less successfully depending on their ability to evaluate and to utilise knowledge (Arora and Gambardella, 1994; Sabatier et al. 2010, p. 3). The following figure outlines the structure of the Biopharmaceutical industry and highlights that it consists of large, medium and small firms.

**Figure 25: The Biopharmaceutical industry structure**



Source: Strength and Opportunity 2011

In the UK the vast majority of Biopharmaceutical firms consist of SME's, which account of 89.87% of the total number of UK life science companies<sup>10</sup>. In addition, even though large Biopharmaceuticals account for 10.13% of the total UK life science companies, the main 25 (GlaxoSmithKline, AstraZeneca, Shire, Pfizer UK for example) firms account for 88.59% of the total annual R&D investment of 2010<sup>11</sup>. This reached £8.42 billion in 2010 as the total R&D investment for that year was £9.5 billion<sup>12</sup>. In a study by Kofinas and Saur-Amaral (2008, p. 258) it has been identified that global knowledge brokers nowadays have put pressure on traditional knowledge creation processes in pharmaceutical R&D, making the use of brokers vital and necessary. Therefore, the study will include the examination of open innovation in the

<sup>10</sup> Strength and Opportunity 2011

<sup>11</sup> UK Gross Domestic Expenditure on Research and Development, 2010

<sup>12</sup> BIS, The 2010 R&D scoreboard - Company data

Biopharmaceutical sector from the point of SME's, knowledge brokers and large firms.

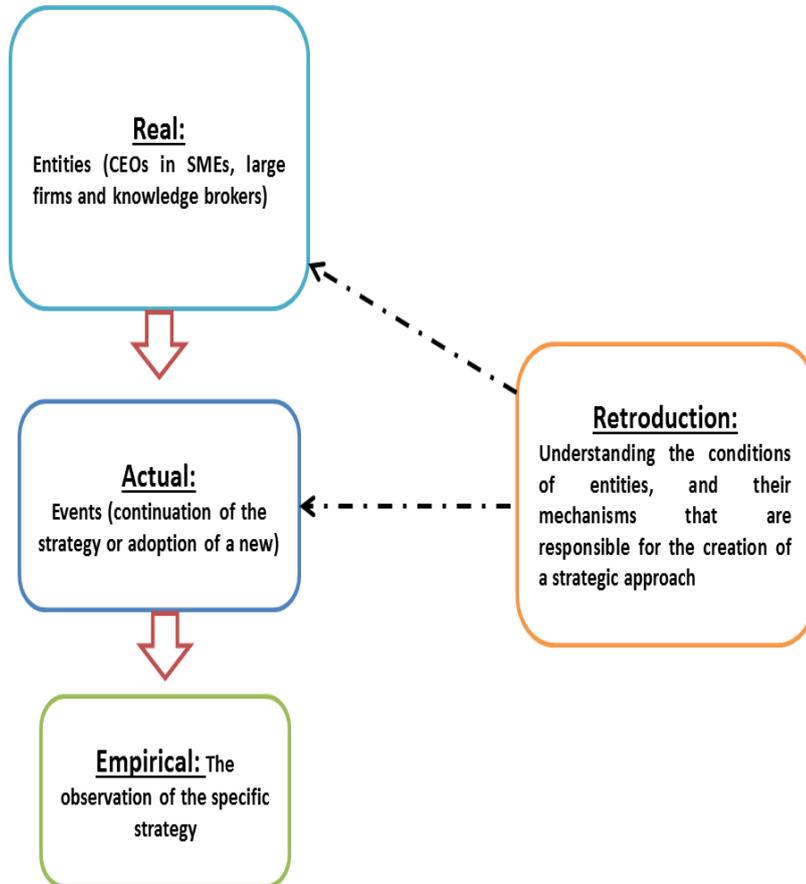
### 3.5.2 Retroductive explanations

Introduced by Peirce in 1903, retroduction is a distinct form of method and logical inference in which hypotheses are produced that are different from deduction or induction. Retroduction is a distinguishing form of scientific interpretation in looking for underlying structures and mechanisms to produce explanations of events in the social reality (Sayer 1992). Foot et al. (2005, p. 73) insisted that retroduction links inductive and deductive research processes and assists in overcoming the duality amongst them. Retroduction reasoning is concerned with why things happen, which includes why data materialises the way it does (Olsen, 2007). Arguably, retroduction has been criticised to be away in how multiple and possible explanations can be established for a single effect based on a retrospective observation of an event, and regularly involves assumptions derived from past observation (Sinkler, 2011). Moreover, it involves the explanation of events in the social world by seeking to separate the structures and mechanisms that are capable of producing them (Blundell, 2007, p. 55). Such practices are concepts initially introduced by Peirce in 1903, which move the researcher in a different direction from the dominant concepts of induction or deduction.

Abduction consists of the study of facts and the development of a theory to explain them (Peirce Vol 5.145 in Hartshorne et al. 1967), as it is the process of forming an explanatory hypothesis (ibid Vol 5.171). At the same time a retroductive conclusion is validated by the explanations of an observed fact, an explanation is a syllogism of which the major evidence, or rule, is a known law or rule of nature, or other general truth (ibid Vol 1.89). The minor premise or case is the hypothesis or retroductive conclusion, and the conclusion or result is the observed (or otherwise established) fact (ibid). The aim of retroduction is not to cover a phenomenon under a generalisation but to identify a factor responsible for it, that helped produce, or at least facilitated it (Archer et al. 1998, p. 156). The goal is to propose a mechanism that, if it occurred and performed in the proposed manner, could account for the phenomenon singled

out for explanation (ibid). Figure 26 depicts the process of structures and mechanisms for the study.

**Figure 26: Retroductive explanation in critical realism**



Adopted by: Archer, 1995

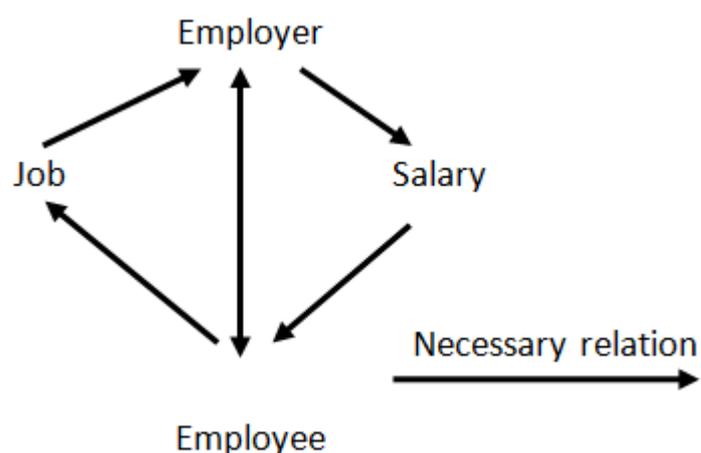
Retroduction is linked to the opportunity of moving from a purely descriptive and abstract analysis of open innovation, to understanding its conditions such as structures, and mechanisms that are seen as key elements of the critical realist perception (Sayer 1992). As it assist in identifying the underlying actors that in a specific combination produce a particular phenomenon or outcome (Lawson, 1997), its use can be applied in identifying the actors responsible for the production or facilitation of a strategic approach (see figure 26). For the purpose of the study, retroduction will be used with the intention to deliberate and recursive processes which involves more than the making of an inference (Chiasson, 2005) to best explain the adoption of open innovation practices in the Biopharmaceutical sector.

### 3.5.3 Elements of analysis using critical realism

Social structures are characterised as ontological real entities (Bhaskar, 1978), thus firms that engage themselves in business activities through the interactions of individuals can therefore be characterised as ontological real entities, as they have emergent powers that create events under particular conditions. Consequently, the study takes into consideration the process of objects as social structures that can change over time, creating a system in which adoption, diversification and a change of business strategy can be studied and understood (Sayer 1992, pp. 104 - 105). For the study, the senior management (individuals as objects) make decisions (fundamental capabilities) that affect the firm's strategy business model (event) towards the adoption of open innovation practices (Levy and Reid, 2011). Strategic decisions, such as choosing to collaborate with an external partner, are social structures that change over time as the collaboration moves forward to completion.

An example of a social structure within a firm is the relationship between the employer and the employee. This type of relationship requires the necessary obligation from the employer to pay the employee and thereby the employee has an obligation to do the work for the employer (Morton, 2006). The necessary relationships are socially structured and can be seen from the example provided in figure 27.

**Figure 27: Social structure of employer and employee**



Adopted by: Morton, 2006 in Sayer, 1992, p. 93.

### Chapter 3- Paradigmatic underpinnings

Dependent relationships between entities are “neither necessary nor impossible” as social structures are emergent entities, which are constituted through mutual social relationships (Sayer 1992, p. 89). Social structures are emergent properties because even though they have been created by the acts of individuals, they then exercise a causal influence over individuals (Archer and Tritter 2000, p. 81).

The emergent powers in a firm are created because this combination of individuals means that their powers become modified in a very fundamental way through their salary and job (Sayer 1992, p. 119). Now, a strategic leadership within a firm may include the role of a CEO, a group of highly ranked members of the corporation such as top management teams (TMTs), as well as the board of directors (Hambrick 1987). The majority of SMEs the owner-manager (CEO) whom receives all cash flows, makes all investment and operating decisions which shape and direct a firm’s learning process (Bierly and Chakrabarti, 1996, p. 123; Brealey and Myers, 2003).

The interpretation of critical realism for this study denotes that Biopharmaceutical SME’s, knowledge brokers and large companies are regarded as social entities that can be understood through the use of critical realist explanations. Within UK enterprises there is a distinct separation of CEO and chairman positions (Dahya and Travlos, 2000). This is due to an enterprise being more stable and experiencing less risk over the long term if they oppose the domination of a single CEO or Chairman (Kaufmann et al, 2005), which has also been recommended in the Cadbury report (Cadbury, 1992).

The aim of social science is to explain social change (Bhaskar 1998a, p. 41) and describe how social forms evolve and why particular outcomes occur (Joseph 2002, p. 177). It also identifies the process through which social change occurs: by the interaction between social structure, culture and agency through “established human practices” (ibid). As a result, decisions towards the adoption of a new strategy are considered as social change that can be explained through a critical realist approach. As the world exists independently of our knowledge of it and knowledge can only be produced in terms of available descriptions or discourses (Sayer 2000), attempting to find available descriptions or discourses for events such as open innovation adoption in

Biopharmaceuticals is reasonable and acceptable. The following section 3.5.4 consists of the interpretation of the research process which consists of a critical paradigm and a retroductive explanation.

**3.5.4 Explanatory view of the research process**

As described in section 3.5.2 retroduction is the way in which “appreciative theorising is developed” (Nelson 1994, p. 292). It establishes the necessary connection between theory and applied work through quantitative and qualitative data (Castellacci, 2006). To identify the structures and characteristics of open innovation in the UK’s Biopharmaceutical industry, the study uses retroduction reasoning, as it is a thorough operation through which one can move from knowledge of one thing to knowledge of something else (Danermark et al. 2002). The retroductive research strategy is associated with the opportunity of moving from purely descriptive and abstract analysis of open innovation to understanding its conditions, such as structures and mechanisms, which are seen as key elements of the critical realist perspective (Sayer 1992). The following table summarises the researchers according to the type of research they have used in critical realism.

**Table 14: Examples of critical realism in empirical research**

<b>Type of research</b>	<b>Action research</b>	<b>Qualitative research</b>	<b>Quant-based research</b>	<b>Case study research</b>	<b>Meta critique - meta theory</b>	<b>Methodologically pluralist explorations</b>
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### Chapter 3- Paradigmatic underpinnings

<b>Examples</b>		Archer (1985)			Bhaskar and Danermark (2006)	
	Floersch (2004)	Carter and Sealey (2000)	Ron (2002)	Chindarkar (2007)	Morgan (2003)	Connelly (2001)
	Lloyd (1995)	Cromby (2004)	Lawson (1989)	Connelly (2000)	Reckwitz (2002)	Langan (2008)
	Warner (1993)	Porter (1993)		Dobson (2001)	Sayer (1999)	Lawson (1998, 1995)
		De Vaujany (2008)		Olsen (2009)	Skinner (2005)	Olsen (2006)
				Ragin (1997)	Clark et al (2007)	Patomaki (2006)

Source: Olsen (2010, p. 19)

To analyse the modes that firms use through their innovation process and validate where open innovation processes are used, it is necessary to describe and distinguish between the traditional and the open innovation model.

- A. “Inbound open innovation”, which is “the practice of leveraging the discoveries of others” and entails the opening up to and establishment of relationships with external organisations with the purpose to access their technical and scientific competences for improving its own innovation performance (Chesbrough and Crowther, 2006)
- B. “Outbound open innovation”, which suggests that “rather than relying entirely on internal paths to market, companies can look for external organisations with business models that are better suited to commercialise a given technology” (ibid).

By dividing the two models (inbound-outbound), the study clarifies the process that firms follow during their innovation progress and application. To investigate the open innovation in Biopharmaceuticals through a critical realist approach, the study utilises the approach of Danermark et al. (2002). This will

start with a description of the study followed by an analytical determination that will lead to the re-description of theories regarding the structures in which individuals relate. Furthermore the study will find, via retroduction, the structures and relations of the individuals within the structure as well as their mechanisms, which will describe the particular adoption. Finally, through a specified envelopment, it will examine how firms and individuals manifest themselves in dense situations such as the adoption of a strategy or the continuation of the current one.

Influenced by Bhaskar (1979), Archer (1995) interprets society as open, stratified and separated, which can be distinguished by three levels:

- VI. Real level, where intransitive structures that are relatively enduring with potential powers and properties are activated as causal mechanisms, when mediated or triggered by human agency.
- VII. Actual level, which is consisted by transitive events that are an effect of social interaction and causal mechanisms.
- VIII. Empirical level, which is transitive, mediated, experienced and observed by our senses.

To engage the analysis of the data it is first divided into three groups. The first group of data is from the SME's while the data from knowledge brokers on the second and large companies in the third group. In order to analyse the data, a stratified ontology that distinguishes the real, the actual and the empirical (Sayer, 2000) can assist in describing explicitly how the data can be obtained in a stratified manner. To collect data for the investigation in open innovation, the study uses a data triangulation through qualitative methodologies known as multi-method or 'within method triangulation' (Denzin 1978, p. 302, Yeung, 1997, p. 64), which is described in detail in section 4.2.1.

### **3.6 Conclusion**

In chapter 3, the ontological and epistemological commitments of the study were identified and discussed, including the difficulties of the researcher in choosing a specific philosophical perspective. In light of the critical realism interpretations of Bhaskar and Sayer, the Biopharmaceutical sector due to its

innovative form, demonstrated why the specific paradigm has been chosen. As the strength of critical realism lies on the fact that it is not bounded by a rationality of a standardised methodology (Mingers, 2003), it gives a better balance between qualitative or quantitative methodologies than other paradigms offer. Therefore, the methodological independence of critical realism offers a wider access to mixed methods research.

The application of critical realism for this study, offers a practical theoretical lenses to inspect the phenomenon of open innovation at all three levels of the social reality: the empirical, the actual and the real level (Bhaskar 1998, p. 16). For that reason a stratified ontology can deliver clear answers to events that, in contrast to other ontologies, are smooth populated by either the actual or the empirical, or a conflation of the two (Bhaskar 1978). The real domain contains the generative mechanisms existing independently from both their activation and the observer (Sayer 2000, p. 12). These mechanisms in the real domain create events, thus establishing the actual domain.

Given the nature of the research objective (the multi-layered investigation of open innovation in terms of opportunities and barriers in the UK Biopharmaceutical industry) and the accessibility of evidence to formulate the relations for the examination, it is considered that a combination of methods is the most appropriate selection for the study. Chapter 4 describes the methodological approaches in social enquiry and the application of methods for the study.

## **4. Methodology**

### **4.1 Introduction**

The purpose of this chapter is to set out the rules and procedures that will guide the research taking into account the paradigmatic foundations of critical realism. The research design will be presented, which includes the goals, research questions, validity and methods. This results from the paradigmatic foundations of critical realism, using retroductive reasoning and utilising a triangulation of qualitative methods.

### **4.2 Methodological grounds**

Methodology implies a set of rules and procedures to guide research and in conjunction with which claims can be assessed, as it is fundamental to the development of all methods of knowledge (Miller and Brewer 2003, p. 192). The role of the methodology is to carry out the research work in a scientific and valid way, as it provides the research and the necessary tools and techniques by which the research objectives will be assessed (Singh 2006, p 79). Methodology is defined as “the study or knowledge (‘-ology’) of methods” and includes, on the one hand, technical instruction in research methods (Bruce and Yearley 2006, p. 196). At the same time, the philosophical reasoning regarding methods and technical study of the operations and consequences of various methods suggests a carefully considered way of approaching the world so that we may understand it better (Sayer 1992, p. 12).

As the study focuses to identify the “generative mechanisms” of nature that exist as the causal powers of things (Bhaskar 1978, p. 50), it can be associated with the adoption of open innovation practices and identified with the use of retroduction reasoning. Olsen (2009, p. 3) identified several methods that are used in realist methodological frameworks, including collecting, analysing and interpreting the data. This will guide the investigation of the adoption and development of open innovation models and strategies in the Biopharmaceutical industry.

**Table 15: Methods within realist methodological frameworks**

<b>Data Collection</b>	<b>Data Analysis</b>	<b>Writing-Up - Interpretation - Elaboration</b>
Questionnaires; Complex sampling and associated survey Methods; Systematic case-study methods; Comparative data collection	Induction (as a technique); Retroduction about data; Qualitative comparative; Analysis action research; Evaluation	Critical social science; Configurational analysis; Explanatory analysis;  Explanatory critique
Historical enquiry; Oral history; Interviewing; Ethnographic research; Participatory research; Gathering texts and translating	Grounded theory; Realist; social statistics; Testing hypotheses (about causal mechanisms and discourses); Explanatory analysis at multiple levels	Critical theorising; Reframing of hypotheses; Pluralist modelling; Re-theorising; Meta-theorising
NVIVO database construction; Qualitative case-study Development; Organising data in spreadsheets	Content analysis; Critical discourse analysis; Retroduction from data to “what must exist in order for these data and these patterns to have been observed?” such as why?; Dialectical retroduction from future to present interpretations	Moral realism; Theoretical pluralism; Dialogue about the good across geographic space and across layers of stratified societies; Methodological pluralism

Source: Olsen (2009, p. 3)

The use of qualitative methods, including in-depth interviews and survey questionnaires, will assess the opportunities and barriers open innovation offers in the UK Biopharmaceutical industry. To investigate the opportunities

and barriers the Biopharmaceutical sector faces during the application of open strategies, a micro - meso - macro context will be employed, to examine the level of adoption in small-medium sized enterprises (SME) and large firms. An overview of the innovation process is that it is the way in which individuals engage in firms' operating functions and the firms' structure and external linkages (Trott 2008, p. 9). For the investigation of the level of open innovation in the UK Biopharmaceutical sector, the study uses a triangulation of qualitative methods, known as within-method triangulation described in section 4.2.1.

#### **4.2.1 Triangulation of methods**

Denzin and Lincoln (2005) maintained that triangulation is not a tool or a strategy of validation but an alternative to validation, which increases the scope, depth and consistency in methodological proceedings (Flick 2009, p. 445). Denzin (1978, p. 291) introduced triangulation as "a combination of methodologies in the study of the same phenomenon", in which a researcher takes different perspectives on an issue under study or more generally speaking in answering the research questions (Flick 2009, p. 445). Moreover, Downward and Mearman (2006, p. 80) stated that Denzin (1970) offers a consistent taxonomy of triangulation, which is now frequently referred to in the literature:

- I. Data triangulation - Combination of different data types.
- II. Investigator triangulation - Combination of insights from different investigators.
- III. Theoretical triangulation - Combination of different theoretical perspectives.
- IV. It has been argued (Downward and Mearman, 2004) that there are two forms of methodological triangulation:
  - H. Within method triangulation - makes use of different varieties of the same method and therefore, in economics, making use of alternative econometric estimators.
  - I. Between methods triangulation - makes use of different methods, such as a mixture of "quantitative" and "qualitative" methods.

Within the sociological community the analysis is widely supported as there is “no universal method and that there is a need for multi-methodological applications” (Danermark et al. 2002, p. 152). Therefore, in the applied social sciences, mixed-methods triangulation (MMT) is common, with adoption in “nursing, health and education, and tourism” (Shih 1998; Hirst 1993, Downward and Mearman 2004). With the use of triangulation, the researcher combines a variety of lenses regarding the project being studied. This enhances the validity of the results and delivers a better or “more substantive picture of the reality” (Berg 2001, p. 5). In-depth, as well as semi-structured interviews may be used in research, either as a stand-alone method or in combination with other methods, which is sometimes referred to as “triangulation” (Longhurst, 2009).

Critical realists such as Lawson, (1997, 2003) Sayer (1992, 2000) and Archer et al. (1998) discard the notion of society and the economy as a closed system. Instead, they argue that reality is a structured open system in which the real, the actual and the empirical domains are organically related (Bhaskar, 1978). This refers to the intransitive dimensions of knowledge that exist independently of our understanding of the world and in which actual structures and causal powers reside. This actually happens when causal powers are activated which access point to the transitive dimension of knowledge, through filtered over the explanatory process. Consequently, critical realism embraces the frailty of awareness and cautions against a “satisfied” link that is being made between what is real and our knowledge of the real (Downward and Mearman 2007). Within the framework of critical realism, retrodution is adopted as it involves a mixture of different research methods that delivers awareness regarding the topic being studied.

### **4.3 Development of Methods**

The word method comes from the Greek word “hodos” meaning “way, route, path or journey”. It is also acknowledged to be a course of action or speech. By combining the word “hodos” with the designation “Meta”, we have methodos a “pursuit, or a special pursuit for knowledge” (Liddell et al. 1940). In our modern society, method is particularly linked with the scientific method that

strongly resonates with *methodos*. It highlights the methodical system of producing and legitimising knowledge, as it is the driving force behind the creation of knowledge (Thorpe and Holt 2008, pp. 129-130). The word “methodology” often refers to the means and procedures used in a discrete piece or a common type of research activity. Mostly, it describes the methods of the investigation, the concepts as well as the underlying analytical arrangements of “a particular academic discipline or sub discipline” (Abercrombie et al. 2006). By having a method we try to describe what is necessary to be done, how it should be done, what data will be needed, what kind of data-gathering tools will be engaged, how the basis of data will be selected, as well as how the data will be analysed and the conclusions that will be illustrated (Singh 2006).

Methodology is defined as “a body of practices, procedures, and rules used by those who work in a discipline or those engaging in an inquiry” (Soukhanov et al, 1992). The role of the methodology is to enable one to carry out the research work in a scientific and valid way. It will provide the research, the necessary tools and techniques by which the research problem will be assessed (Singh 2006, p. 79). There is a diversity of methodologies that can be used in an innovative research but clearly defining the methodology is an important process in research “*as it is significant, since the methodology will determine the outcome*” (Hine and Carson 2007).

#### **4.4 Qualitative research design and methods**

All qualitative researchers are philosophers in the general logic where all human beings are guided by highly abstract principles (Bateson 1972, p. 320). The particular principles combine theories about ontology (what is open innovation and what is the nature of open innovation?), epistemology (what is the relationship between the open innovation and innovation?) and methodology (how do we know open innovation or gain knowledge of it?) (Denzil and Lincoln, 2005, p. 22).

As qualitative research is a field of enquiry it crosses through disciplines, fields as well as subjects. The terminology of qualitative research is complex as it inter-relates a wide spectrum of terminology, a wide context and several

97

assumptions. The word 'qualitative' covers largely non-statistical approaches for data collection and analysis. Quantitative work however, tends to limit its scope in finding out what exists from a perspective of distance (by isolating variables) and of averaging occurrences through numerical studies. Qualitative work looks to uncover what exists by involvement and therefore to accept the ensuing complexity and difference of using affluent descriptions (Thorpe and Holt 2008). A qualitative project typically requires the researcher to immerse themselves in what they are studying in various ways. For example, by creating a dialogue, whereby they are either physically removed (telephone interviews or postcards) or in a complete and sustained engagement (Thorpe and Holt 2008).

The use of qualitative investigation refers to approaches towards empirical inquiry that "collect, analyse, and display data in numerical rather than narrative form" (Given 2008). Additionally, it seeks to answer questions by examining different social settings and the individuals who occupy them (Berg 2001). Bryman (1988 p. 8) stated that "the means in which people are being studied understand and interpret their social reality is one of the central motifs of qualitative research". Various data collection methods have also been identified with qualitative research such as: observational methods, in-depth interviewing, group discussions, narratives and the analysis of documentation (Bryman 1988; Denzin and Lincoln 2000; Hammersley and Atkinson 1995; Holloway and Wheeler 1996; Mason 2002; Miles and Huberman 1994; Patton 2002). Nevertheless, it is important to note that practitioners of qualitative research vary significantly in the extent to which they rely on particular methods of data collection (Ritchie and Lewis 2003). Additionally, it allows a phenomenon to be examined within its real life environment (Bonoma 1985; Yin 1994) due to the holistic view case study methods present (Gummesson 1991; Hofer and Bygrave 1992; Rocks et al. 2007).

Among the various methods in qualitative research, the context of interviewing has been widely used in "*marketing research, political opinion pooling, therapeutic reasons as well as for an academic analysis, as a tool of measurement*" (Denzin and Lincoln 2000, p. 646). Structured or semi-structured interviews are an important and direct way of obtaining information,

either individually or within focus groups within the firm (Hine and Carson 2007, p. 205).

The advantages of using in-depth interviews are (Hine and Carson 2007, p. 37):

- I. It covers a wide range of interests, which helps the researcher to become familiar with the areas of interest in the research process.
- II. It enables the researcher to identify and explore the key issues and elements of the research as they are revealed, due to the open nature of the interview.
- III. It allows the opportunity for further questioning and investigation until a mutual understanding has been reached.

Hine and Carson (2007, p. 39) also suggest that a qualitative study can include:

- A survey of Entrepreneurs, Owners, Managers in a particular industrial context.
- In-depth interviews with “key-informant” owners and managers.
- Observations of the business activity of a particular firm.
- Data comparison of competitive activity.
- Analysis of the company’s appropriate records.

Qualitative methods can be a combination of the above, which allows the researcher to get much closer to the phenomenon and can be adopted to suit the specific context of the individuals under a particular study (Gilmore and Carson 2007). Another important tool in gathering information is the web, as it is now an important path of business. Companies that do not take it seriously raise significant drawbacks in the eyes of a user. The user has very little patience for poorly designed websites, which should suggest to firms that their website must contain a balanced combination of information and good design (Potts 2007). What firms consider important nowadays is the necessity to have a constantly updated website, which will include the latest news regarding the firm’s activities, annual meetings and press releases.

Several studies utilised qualitative methods for the investigation of open innovation, such as interviews, surveys and focus group discussions

(Chesbrough and Crowther 2006; Dahlander and Gann 2010; du Chatenier et al. 2010). Chesbrough and Crowther (2006) used survey designed interviews to determine that open innovation practices, systems, roles, and responsibilities can help to ensure successful adoption across the organisation. Similarly, Dahlander and Gann (2010) developed a study using qualitative techniques in identifying and analysing the advantages and disadvantages of different forms of openness. In addition, du Chatenier et al. (2010) used interviews and focus group discussions in their study to provide a competence profile for open innovation professionals.

For development of the research, resources were gathered in a primary form and conducted in 3 phases:

- a. Phase 1 - Preliminary: 30 Semi-structured in-depth interviews (Selective Sampling - Cross sectorial - SMEs)
- b. Phase 2 - Following: 8 Semi-structured in-depth interviews (Selective Sampling - Cross sectorial - Knowledge Brokers)
- c. Phase 3 - Final: 12 Survey questionnaires (Selective Sampling - Cross sectorial - Large Biopharmaceuticals )

The following sections 4.4.1 and 4.4.2 describe the use and applications of two data collection approaches, namely interviews and survey methods.

### **4.4.1 Interviews**

The importance of oral history is that it embraces and describes the “story of one person’s life or a collection of individual stories told together, the power resides in the meaning made of the storytelling and what we learn from the stories” (Janesick 2010, p. 1). The interview can be described in terms of individuals that are directing their attention towards each other. Their single purpose being to open up the possibility of gaining an insight into the experiences, concerns, interests, beliefs, values, knowledge and ways of seeing, thinking and acting (Schostak 2006). Moreover, Heron in 1981 pointed out that interviewing is a basic mode of inquiry. Oral history has been defined to be the collection of stories and reminiscences of a person or persons who have first-hand knowledge of any number of experiences (Janesick 2010).

Janesick (2010) argues that a rewarding component of using interviews is that it has a creative act and often requires the use of imagination in doing so. The importance of using an interview model as a major source of data collection has been discussed by many authors as being the main purpose of gathering information (Denzin 1978; Spradley 1979; Patton 1980; De Santis 1980; Lincoln and Guba 1985; Salkind 1991; Frankfort-Nachmias and Nachmias 1996; Babbie 1992, 1998; Leedy 1993; Marshall and Rossman 1999). How well the interviewer performs the aspects of sampling and gaining co-operation plays an important role in coverage and non-response errors. Therefore, since co-operation is one of the most difficult tasks for interviewers to accomplish in general population surveys, it is a significant topic for both interviewer training and on-going supervision as the interviewers affect data quality once someone has agreed to be interviewed (Groves et al. 2004). Patton (2002) argued that the reason of interviewing is to allow the interviewee to enter into the interviewers' perspective. A reason for in-depth interviews being so popular is that they are very effective in giving a human face to research problems (Mack et al. 2005), as the intention of it is to gather information (Berg 2001). Interviewing is an important tool as the interest is in other people's stories, as the interview is a basic form of inquiry (Seidman 2006, p. 7). Stories are a way of knowing, as the roots of the word would suggest: 'story' is the Greek word 'histor', which represents one who is 'wise' and 'learned' (Watkins 1985, p. 74).

Interviewing techniques are very popular in the research in open innovation. A good example is Chesbrough's (2003a, p. 4) use of interviews with current and former managers that enabled him to conclude that Xerox (a document management corporation) problems with PARC (information technology and hardware Systems Corporation) arose from the way its innovation process was managed. For the study, interviews will be used to acquire information from CEO's of SMEs about the level of innovation and openness in their firms, and interviews with knowledge brokers in an attempt to investigate the tendency of the Biopharmaceutical sector towards the open innovation concept.

### **In-Depth Interviews:**

In-depth interviews are useful for learning about the perspectives of individuals, as opposed to, for instance, a group model of a community, where focus groups are more appropriate. It is an effective qualitative method for getting people to talk about their “personal feelings, opinions, and experiences”. In-depth interviews are also an opportunity for the researcher to gain an insight into how people interpret and order the world, as in-depth interviews are generally conducted face-to-face and involve one interviewer and one participant (Mack et al. 2005).

To obtain detailed information about a person’s thoughts and behaviours or to explore new issues in depth, in-depth interviews are to be utilised (Boyce and Neale 2006). This approach primarily uses open-ended questions to build upon and explore the participants’ responses to those questions. The goal is to have the participant reconstruct his or her experience within the topic that is being studied (Seidman 2006). The interview data will consist of tape recordings, typed transcripts of tape recordings, as well as the interviewer’s notes; from this, the typed transcript are the most utilised form of interview data (Mack et al. 2005).

Seidman (2006, pp. 17-19) argues that there are three major successions when using in-depth interview:

- To focus on the life history of the interviewee. This means that the interviewer’s duty is to set the participant’s experience in context by asking him or her to inform them as much as possible about him or herself in light of the topic at the present instance.
- To concentrate on the concrete details of the lived experience of the interviewee within the subject area of the study.
- To reflect on the meaning of their experience. This addresses the intellectual as well as the emotional connections between the participants’ work and life.

In the context of this study, interview methods have been used to acquire information from SME’s senior management and knowledge brokers from the Biopharmaceutical sector, regarding the processes of innovation, including research & development, intellectual property as well as co-development. As

interviews are face-to-face verbal exchanges between the individuals, it is possible to capture the experiences and perspectives of CEO's from SMEs and knowledge brokers regarding their innovation practices in their firms and in the sector. By doing so, the study will reveal and demonstrate the processes and relationship between SMEs large firms and organisations. Furthermore, through the interview process the study will identify the fundamental properties and aspects of open innovation, such as in/out source, IP in/out source and open collaborations as well as where, how and why.

#### **4.4.2 Survey Data**

In recent years surveys are being used routinely by governments, businesses, academics, politicians, the news media, those in public health professions, and numerous other decision makers (Lavrakas 2010, p. xxxv). Survey research is described as a systematic set of methods used to gather information to generate knowledge and to help make decisions (ibid). Bryman (1989, p. 85) stated that the use of social survey is conventionally associated with questionnaires and interviewing. He argues that survey research entails the collection of data that occurs on a number of units and usually at a single moment in time. This data is invariably in the field of organisational research by self-administered questionnaires or by structured or possibly semi-structured interviews.

Survey is a research method used by social scientists such as economists, political scientists, psychologists and sociologists, to empirically and scientifically study and deliver information about people and social phenomena. Therefore a survey is scientific due to the fact that there is an established process that can be followed, documented, and replicated (Lavrakas 2010, p. 860). The capacity for its wide application and broad coverage gives survey techniques a great usefulness over other methods as it does not belong to any field and it can be employed in most disciplines (Campbell and Katona 1953, p. 16). The goal of a survey is to produce a 'snapshot' of the opinions, attitudes or behaviours of a group of people at a given time (Stangor 2010, p. 107). Since surveys can be used to gather information about a wide variety of information in a relatively short time, they

are employed extensively in marketing advertisement and even in politics when politicians try to ascertain what voters think, feel, or do (ibid).

An example of the use of the survey method can be found in Kamien and Schwartz (1975, p. 31), where they reviewed the empirical literature on the relationship between resource allocation to R&D and technical advance in the study of market structure and innovation. Van Cayseele (1998, p. 417) re-examined the contributions made by others on Kamien and Schwartz's that have been developed over the last 20 years (1975-1998). In his review of the application of antitrust enforcement, or in providing the micro foundations for the modelling of economic growth on a theoretical front, the research identified that Kamien and Schwartz's method lagged remote behind theory on the empirical front. A particular example of survey method can be found in Hofstede et al. (1990), who used qualitative (interviews and questionnaire surveys) and quantitative methods to collect and measure data on organisational cultures in Denmark and the Netherlands.

In open innovation research, Chesbrough (2003a, p. 161) used survey methods for the Xerox case to identify the level of open innovation strategies and tactics that were used by the company. Furthermore, surveys were utilised by Laursen and Salter, (2006) that linked search strategy to innovative performance based on a new model of innovation. Additionally, as the interest increased several scholars' utilised surveys for their research in open innovation adoption. In particular, Van de Vrande et al (2009), effectively measured innovation practices, reflecting the technology exploration and exploitation in SMEs using survey methods. Moreover, Chesbrough and Crowther (2006), who identified through their survey organisations in industries besides high-tech that are early adopters of the open innovation concept. Van der Meer (2007) also surveyed the adoption of open innovation in Dutch companies, support the use of survey methods for the research in open innovation. By use of survey questionnaires, the study will gather and provide primary information regarding the level of open innovation that exists in large biotech and pharmaceutical companies who are the early adopters of open strategies.

In the context of this study, survey methods have been used to acquire information from the senior management of large Biopharmaceutical firms,

regarding their processes of innovation, including research & development, intellectual property as well as co-development. Through the survey process the study identifies the properties and aspects of open innovation, such as in/out source, IP in/out source and open collaborations as well as where, how and why large Biopharmaceutical engage in open innovation.

The following section 4.5 explains in detail the data collection process, which includes the justification of the method triangulation.

## **4.5 Data collection approach**

The study uses multiple data sources from interviews and survey questionnaires, as this enables information to be gathered regarding the progress of firms during their innovation processes and the relation this has to open innovation practices. The samples of SMEs and large Biopharmaceutical firms have been selected not because of their size, but also because they are member of ABPI (Association of the British Pharmaceutical Industry) and BIA (BioIndustry Association). These associations are regarded as promoters and representatives of innovative research-based Biopharmaceutical companies<sup>13</sup>. As to the sample of knowledge brokers, it was selected based on the recommendations of the spokespersons of the ABPI (Association of the British Pharmaceutical Industry) and BIA (BioIndustry Association), as well as the suggestions of the Research & Innovation Services of the University of Southampton. The University of Southampton is a member of BIA, therefore it was recommended to approach the interviewees directly in a form of co-member enquiry. Table 16 outlines the data collection method in relation to the sources for this research.

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<sup>13</sup> Association of the British Pharmaceutical Industry - About us (<http://www.abpi.org.uk/about-us/Pages/default.aspx>)

**Table 16: Data gathering approach**

Phase 1:	Open innovation in SME's	Semi-structured interviews
Phase 2:	Knowledge Brokers - Gatekeepers involvement and relation between SME's and Large companies	Semi-structured interviews
Phase 3:	The existence of open innovation in large Biopharmaceutical companies	Survey questionnaires

As the research embraces a critical realism perspective the use of the within method triangulation approach matches with the paradigm. It will reveal the causal mechanisms concerning “how” and “why” open innovation practices and strategies are utilised. The following section 4.5.1 clarifies the application of the data collection for the study.

#### **4.5.1 Application of data collection for the study**

The significance of open innovation in social practice has created an intention, which is defined as a “general enquiry” within the management research (Thorpe and Holt 2008). The study develops an explanatory micro - meso - macro ecosystems to examine real-life circumstances, which are structured through multiple data sources of interviews and surveys and are assembled as follows:

The primary reason for utilising semi-structured interviews was to assess the opportunities and the barriers associated with open innovation practices; in particular interviews with CEOs of Biopharmaceutical SMEs (coded SME), and knowledge brokers (coded KB) who have an intermediate function between firms’. Moreover, questionnaires were used for senior managers of large Biopharmaceutical firms, consisting of 12 respondents from 10 different large Biopharmaceutical firms and organisations (coded LF). As pointed out in section 4.2.1, a triangulation of tools for data collection has been employed including:

1. Semi-structured in-depth interviews
2. Online questionnaires

The individual respondents represent SMEs and knowledge brokers in a selective cross-sectorial sampling, and the online surveys representing large Biopharmaceuticals are also collected using a cross sectorial selective sampling. Table 17 illustrates the data collection strategy based on the triangulation of different sources and collection methods, and the issues in each phase as follows:

**Table 17: Data Collection Strategy**

<b>Primary: 30 Semi-structured in-depth interviews with CEOs of SMEs (Selective Sampling - Cross sectorial) (July 2011 - January 2012)</b>			
Position and Number of Respondents	Issues Towards Data Collection and Establishing Contacts	Location and Time Per Interview	Data Collection Notes
CEOs - 24; Business Development Manager - 2; Founding Director - 1; R&D Director - 1; Chief Science Officer - 1; Chief Operations Officer - 1	Time constrains were always an issue as the senior manager in SME were particularly busy with the firm	Abingdon - 3; Cambridge - 6; Fareham - 1; Little Chesterford - 1; London - 4; Loughborough - 1; Macclesfield - 1; Manchester - 2; Nottingham - 2; Oxford - 2; Reading - 1; ;Salisbury - 1; Southampton - 2; Trowbridge - 1; Winchester - 2 / Duration: 45	Interviews kept in a formal and semi-structured way, allowing the respondents to discuss their approach regarding their innovation process
	Identifying the particular individuals was time consuming		The researcher was in control of the interview in order to make sure that the questions were answered by the interviewees

		minutes - 1 hour	appropriately
	All interviews with senior management of SMEs were conducted at their respective offices		Senior management of SMEs were protective regarding their innovation processes and additional questions were introduced
<b>Follow up: 8 Semi-structured in-depth interviews with Knowledge Brokers (Selective Sampling - Cross sectorial) (December 2012 - April 2013)</b>			
Position and Number of Respondents	Issues Towards Data Collection and Establishing Contacts	Location and Time Per Interview	Data Collection Notes
Knowledge Brokers - 6; Industrial Experts - 2	Issues Towards Data Collection by Establishing Contacts were always present	London - 5; Southampton - 2; Dorset - 1	Interviews kept in a formal and semi-structured way, allowing the respondents to discuss their approach regarding their innovation process
	Timing issues were important as the arrangement for an interview took from 2-4 weeks		The researcher was in control of the interview in order to make sure that the questions were answered by the interviewees

			appropriately
	All interviews with knowledge brokers and industrial specialist were conducted at the place of their choice		Knowledge brokers and industrial experts gave a thorough explanation of the industry and the position of open innovation in the Biopharmaceutical sector
<b>Final: 12 Online surveys from CEOs and Directors of large firms (Selective Sampling - Cross sectorial) (March 2012 - June 2013)</b>			
Position and Number of Respondents	Issues Towards Data Collection and Establishing Contacts	Location and Time Interview	Data Collection Notes
CEOs - 5; Head of R&D operations - 1; Directors - 3; President of Association - 1; Research fellows - 2	The pilot survey conducted to test the questionnaire and address possible issues was time consuming	On-line survey	The survey identified several aspects large Biopharmaceuticals consider during the progress of their strategies
	Making contacts was time consuming as the study was promoted to senior managers of large Biopharmaceutical		The survey identified why and how large Biopharmaceuticals consider open innovation as a

	firms		strategy
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Source: developed by the author

To evaluate the business models applied in the Biopharmaceutical industry; this study includes the actual situations and events of which CEOs, directors, knowledge brokers and industrial specialist undergo during the research and development process. This will reveal how the business activities develop to actual approaches. It has been argued that the strategic decision-making process is ambiguous, complex, and unstructured, thus the perceptions and interpretations of senior management teams members critically influence these strategic decisions (Dutton and Duncan, 1987; Wiersema and Bantel, 1992, p. 92).

#### 4.5.2 Multi-layered approach “Micro - Meso - Macro”

With the use of a multi-layered approach, the study seeks out a deeper understanding of the conditions in which firms “embrace” open innovation strategies, as well as the context of how they conduct business within the specific framework. It was clarified that the use of a multi-level as an analytical and exploratory conception in understanding the socio-technical change is imperative when addressing the characteristics of an innovation system (Geels, 2002, p. 1259). With the use of a ‘micro - meso - macro’ approach the research has three main aims: firstly to reveal the level of collaboration and interaction firms have with regulatory bodies in a national and international level (macro); secondly to capture the relation that exists between firms and other institutions (meso) and thirdly to identify how firms interact with individuals and the impact of this (micro).

Within the context of a multi-layered approach, the study tries to capture the value that can be created when using open innovation models and the way in which that is possible, as such options can completely diversify a firm’s R&D budget. In addition, it will provide an insight as to where open innovation is been perceived as a fad or trend within the management discipline, as comparable with the Total Quality Management, Reengineering, Management by objectives and Six Sigma during the past 20 years, for example. The fast

growing field of open innovation could be regarded as a fad (Miller and Hartwick 2002; Carson et al. 1999) or as a useful tool that firms can adopt. This raises the question to firms adopting open innovation practices, as to how its implementation becomes beneficial in terms of increased revenue and cost deduction, as well as management clarity.

## **4.6 Choosing the Outline**

Several methods have been identified that can use a realist methodological framework which can collect, analyse and interpret the data (Olsen, 2009, p. 3). The study utilises a within method triangulation, such as in-depth interviews (qualitative) and survey questionnaires (qualitative). The intention is to design a study that combines in-depth interviews with the senior management and executive contacts of SMEs and knowledge brokers and survey questionnaires to directors based in large Biopharmaceuticals. From the literature it would appear that large companies are among the pioneers of open innovation practices (Chesbrough 2003a, p. 206), whereas SMEs have been largely neglected. This will help to gather as much information as required regarding each firm's innovation processes, as retroduction will identify the actors (individuals) responsible for the existence of open innovation practices. Furthermore, it will confirm whether firms changed their activities when open innovation practices were applied, by providing the necessary information concerning the reasons in which open innovation occurs. Through this, the study will bring to light the difficulties firms face, as open innovation requires the interaction with external associates, resources and technologies.

The inclusion of industry brokers (gatekeepers) will play a significant role in identifying whether there is any influence of exchanging ideas between brokers and large companies; and if so, how that affects the relationship between SMEs and large Biopharmaceuticals. The data will be collected through semi-structured interviews and survey questionnaires with CEO's and directors of SMEs and large companies as well as knowledge brokers. This will verify and validate the attitude and the strategies of SMEs and large Biopharmaceutical firms towards open innovation.

An aspect which has been indicated in this chapter is the non-utilisation of a case study. This occurs as the main principle to investigate the Biopharmaceutical sector, rather than generating assumptions, since other methods are more suitable for that purpose (Flyvbjerg, 2006, p. 27). This is better explained by Stake (1978, p. 6) who argued that the case study will often be at a disadvantage if the aims of the inquiry is to explain, propose knowledge and law. Moreover, case studies have been criticised as they provide greater difficulty to generalise from a single case, thus enhancing the research bias (Simons, 1996, p. 237). In addition to that, as the industry is populated by several subsectors such as biotech, pharmaceutical, medical devices, pharmacokinetics and diagnostics, their innovation cycles vary. This means that the use of case study will increase bias as although the firms are in the same sector (Biopharmaceutical), they have different technological progressions, which vary from short to long term (see table 19).

### **4.7 Conclusion**

The suitability of triangulation strategy is presented in light of the components of critical realism and its interpretations to this research. It implies that different methods are combined to provide matching understandings into the phenomenon of open innovation with the intention of enhancing the validity of results (Modell 2009, p. 209). Chapter 4 defined the application of various methodological tools for the studying the open innovation concept, through qualitative methods such as in-depth Interviews and survey questionnaires. Chapters 5 discuss the processes in which the data were collected, analysed and presented.

## 5. Analysis

This chapter shows how the analysis and discussions address the three main research objectives and the associated research questions (1-14) specified in the methodology chapter. The analysis of the data is divided into three parts:

- 1) Exploring the concept of open innovation in the Biopharmaceutical sector, by focusing on specific entities (CEOs, CSOs, and Directors) that are directly linked to the processes of SMEs.
- 2) Accessing the viewpoint of individuals with specific skills such as knowledge brokers and intermediaries.
- 3) Capturing the attitude and the reasons of large Biopharmaceuticals towards the open concept.

To develop an understanding of the adoption of open innovation in the UK Biopharmaceutical industry, the study approached a variety of organisations and individuals. The purpose was to expand the participant portfolio across the UK to validate that the selected firms and organisations are recognised within the industry. The study assessed the following sources:

- 1) Small and medium enterprises, members of ABPI (Association of the British Pharmaceutical Industry) and BIA (BioIndustry Association)
- 2) Knowledge brokers – Intermediaries of innovation (industrial specialists)
- 3) Large Biopharmaceutical firms and organisations, members of ABPI (Association of the British Pharmaceutical Industry) and BIA (BioIndustry Association)

The scope of the analysis conceptualises, codes, and categorises the strategic decisions, collaborating procedures, intellectual property structure and management of the firms (including individuals and entities such as academics, firms, institutions and government organisations), which are elements of openness according to Chesbrough (2003a). Within this, the study focuses on the conceptualisation of openness based on the perception of senior managers of Biopharmaceutical firms, and codes and categorises openness based on the procedures introduced by Chesbrough (2003a).

It has been argued that open innovation allows externally developed inventions by the participation of firms and or individuals to attract venture capital, or to involve educational investments in promising projects at universities or research organisations (Chesbrough, 2003a). Consequently open innovation can be seen as a model that allows companies to acquire improvements within a wide range of externally developed inventions and a way of dealing with new business models (Vanhaverbeke, Van de Vrande and Chesbrough, 2008). As technological change happens through the deliberate diversion of resources to activities through R&D activities (Kennedy and Thirlwall, 1972), it is considered one of the main generators of technological progress (Howells, 1994, p. 13-14).

The main goal of the data collection was to create an understanding of the elements of open innovation adoption within the Biopharmaceutical sector (research objectives 1, 2, 3). Being influenced by the use of critical realism in developing the conceptual framework and the research questions, the study utilised semi-structured interviews and questionnaires for the data collection. Its other goal was to generate a focused and relevant understanding of the role of the individual; the firm and the context within which these firms operate; and how the elements and structure of a firm can come together and shape open innovation.

- Phase 1 - Preliminary: 30 Semi-structured in-depth interviews (Selective Sampling - Cross sectorial - SMEs)
- Phase 2 - Following: 8 Semi-structured in-depth interviews (Selective Sampling - Cross sectorial - Knowledge Brokers)
- Phase 3 - Final: 12 Survey questionnaires (Selective Sampling - Cross sectorial - Large Biopharmaceuticals)

**Table 18: Research Objectives**

Objective: 1	Explore the processes and relationship of and between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies
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Objective: 2	Demonstrate the significance of open innovation strategies in terms of its fundamental properties and aspects, such as in/out source, IP in/out source and open collaborations.
Objective: 3	Explain how critical realism assist in studying and explaining the structure of open innovation processes within the Biopharmaceutical sector

The research objectives identify the development of an ecosystem between SMEs, knowledge brokers and large firms. Furthermore a comparison will be created between SMEs, knowledge brokers and large firms of the Biopharmaceutical industry.

The first part of the analysis covers a full examination of SMEs, and aims to identify the existence and the level of adoption of open strategies when SMEs engage their business models. In doing so, the study categorises seven main elements of open innovation based on Chesbrough's (2003a, 2006) account:

- Business strategy and innovative approaches
- Collaborative processes
- Research and development capabilities
- In-outsourcing activities
- In-out licencing
- Intellectual property
- Engagement with brokers and agents

For the purpose of this study, semi-structured interviews with CEOs, directors and senior management individuals were conducted across 30 SMEs from the UK Biopharmaceutical industry. The interviews were processed and encoded using Nvivo qualitative software, and the coding was structured around the interview questions to classify, sort and arrange information to examine relationships in the data (NVivo 10 guide, 2013). The study classifies the approaches of SMEs, knowledge brokers and large firms towards open innovation by developing word tree clusters to elucidate links signifying how

and why open strategies occur. Microsoft excel was also used to create visualisations of the adoption, utilisation and progress of innovative approaches used by SMEs and large firms, as well as the perspective of knowledge brokers regarding the progress of the UK Biopharmaceutical sector.

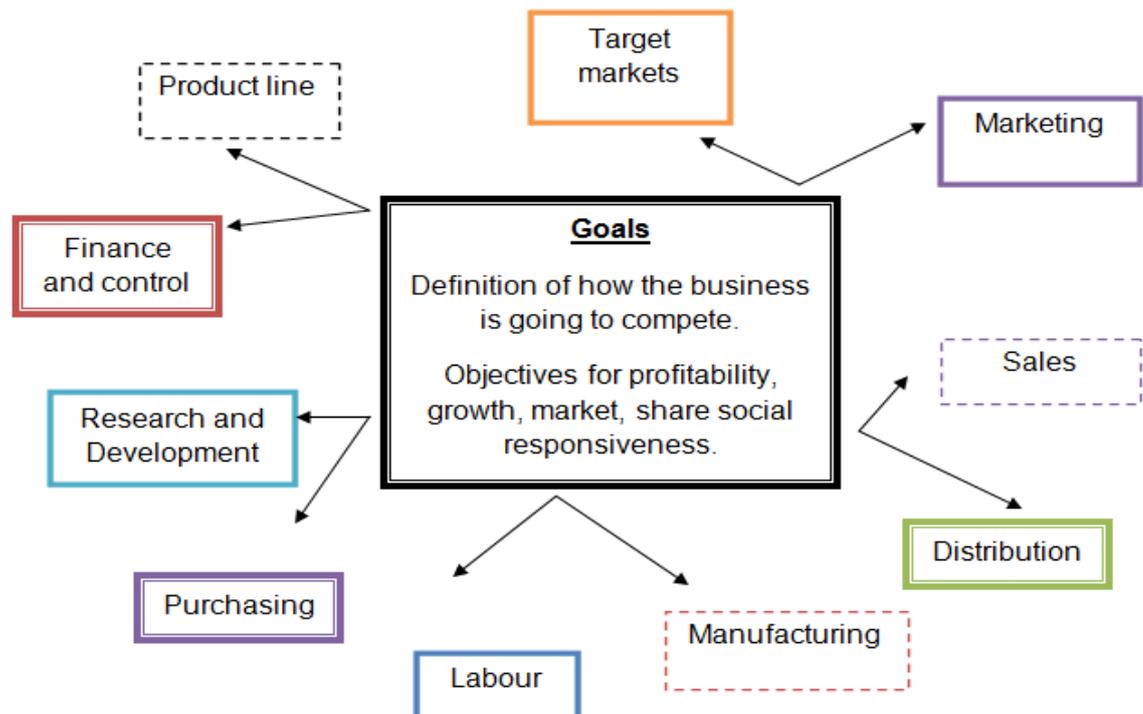
In chapters 6, 7 and 8, the study reviews the main evidence and findings from the research interviews with CEOs from SMEs and knowledge brokers, and the survey from CEOs in large Biopharmaceuticals, at a micro, meso and macro levels in each instance.

## 6. Open innovation in SMEs

As Porter (1996, p. 64) put it, “the essence of (competitive) strategy is choosing to perform activities differently than rivals do”. Therefore, making ground-breaking strategic decision-making can lead a firm into a variety of approaches, in which open innovation can have a protagonist role. For a pharmaceutical company, innovation is a significant driver for the discovery of a new molecular entity up to and including marketing approval (Parsons, Jackson and Dawson, 2006, p. 2). To assess the attitude of SMEs towards innovation the study considers their strategy in terms of process and progress.

To evaluate a firm’s environment, the study defines the firm’s external boundaries which reflect the impact of government policy and social concerns factors; this factor must be considered before a business can develop an accurate and feasible set of goals and policies that assist in the completion of a firm’s goals (Proctor, 2000, p. 13-14).

**Figure 28: The wheel of competitive strategy**



Source: Porter, 1998, p. xxv

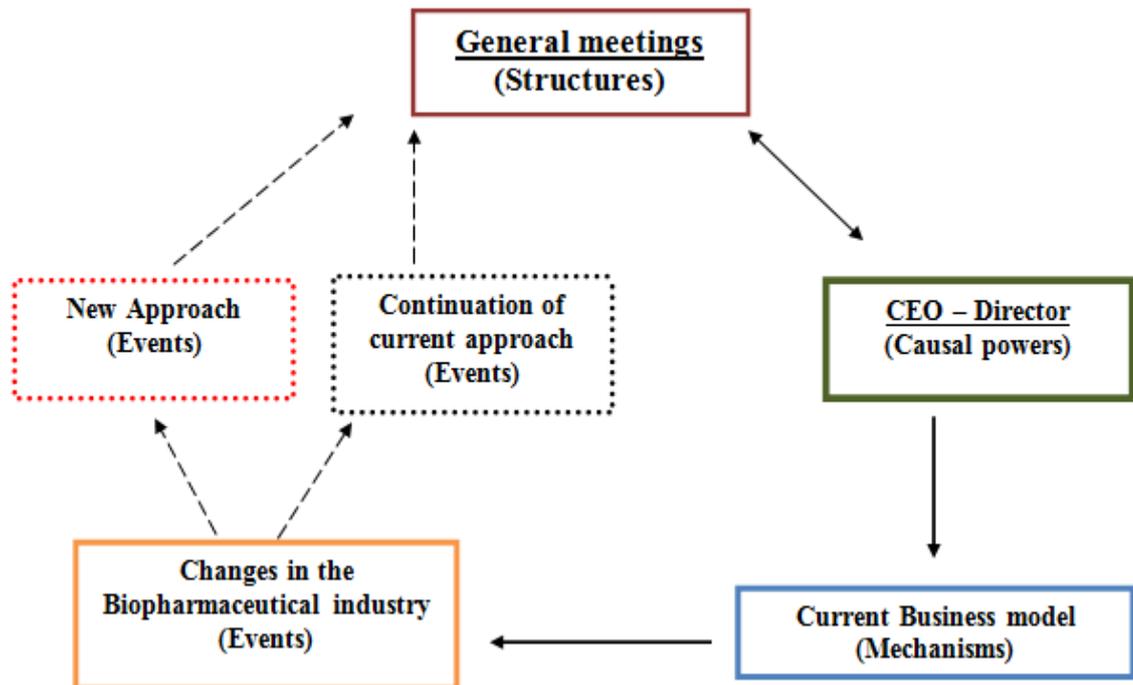
To understand fully how innovation is expressed, the study first examines the relationships between the senior management of firms that exert certain/identifiable causal powers and liabilities. In doing so, they create mechanisms that lead to events such as the continuation or the adoption of a new business approach. Table 19 categorises the distribution of SMEs across the life science sub-sectors.

**Table 19: Position of SMEs in the Biopharmaceutical industry**

<b>Sector</b>	<b>No of Firms</b>
<b>Bio Market Discovery</b>	1
<b>Biopharmaceutical</b>	4
<b>Biotechnology</b>	4
<b>Diagnostics</b>	1
<b>Drug Discovery</b>	1
<b>Medical Devices</b>	1
<b>Pharmaceutical</b>	13
<b>Pharmacokinetics</b>	1

In figure 29, the study pinpoints the structural process of strategy that was identified in figure 28, in which innovation is seen as a strategy and adopted or implemented by a firm, and how that mechanism works from a critical realist viewpoint.

Figure 29: Critical Realist View of Strategy Process Structure in SMEs



Adopted from: Sayer, 1992, p. 93

Figure 29 explicitly illustrates how in an intransitive domain, the stratification of an entity (SMEs) through its particular structures (such as general meetings - CEOs), has causal powers which can create particular decisions. These specific decisions, through their necessary and dependent relations (internal and external factors), when exercised, deliver the on-going process of the current business model or favour the adoption of a new and more open approach. The micro-meso-macro framework is used as an analytical approach (Dopfer and Potts, 2004), to detect the evolutionary nature of a structure, by identifying the actual arrangements Biopharmaceutical SMEs employed during their innovation developments, the mechanisms that trigger the events, and in which way. For example:

- i. At the micro level, the study locates the main objectives that drive a company's approach towards innovation, as SMEs are considered to be competent and prompt in adjusting to the changes of the industry.

- ii. On the meso level, it identifies how SMEs are influenced by the industrial competition with other SMEs, large Biopharmaceuticals or from various links with partnering companies, institutions and academic groups.
- iii. On the macro level, it detects the impact of national, international funds and government bodies during the innovation process of SMEs.

From the multi-layered perspective, the study with the use of retroduction reasoning can trace and identify the actors and mechanisms that are responsible for producing and facilitating innovation and open strategies in the Biopharmaceutical sector.

## 6.1 Innovation as a strategy in SMEs:

The innovation strategy of Biopharmaceutical SMEs ranges from totally closed to fully open, with significant variation between these limits.

Innovation has been defined as the process of introducing new ideas to the firm in which results can increase a firm's performance (Rogers, 1998) and has been said to be the engine of growth and development (Trott, 2005). The firms in the study have a progressive attitude towards innovation, which can be found in several motives and examined through critical realism, by identifying the relationships and causality of their strategy. To access the level of innovation in SMEs the study formulates questions regarding the approach of firm towards innovation as a part of their strategy.

In recent times, the biotechnology sector has become a driving force for fundamental change in innovation processes, as the traditional pharmaceutical industry is replaced by a new biotechnological paradigm and "the traditional chemical paradigm of drug discovery and development seems to be banned" (OECD, 2006, p. 9). To illustrate this point, a senior manager at one SME defined innovation as:

*"An approach that generates an original technology through our existing and or new ideas" (SME-01)*

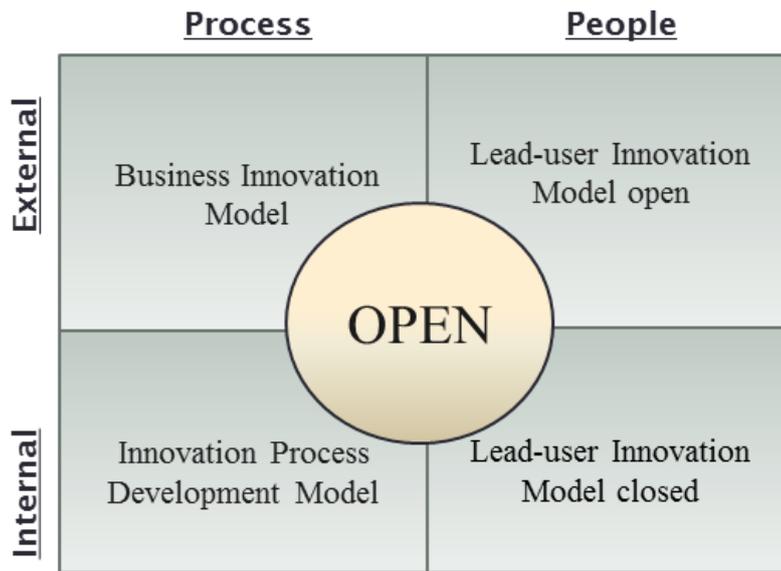
This also highlights the approach SMEs have towards innovation, as the creation and distribution of knowledge are "the most valuable intangible assets

of a firm” (Chan Kim and Mauborgne, 1998, p. 323), and are believed to be the most valuable skills of a firm. The senior management of SMEs in this study acknowledged innovation as the most significant part of their process and it is treated with high importance and key to product innovation through an open innovation network model. Innovation can also be found during and within the course of the various processes of a firm, such as the research and development as well as the diagnostics phase. Improving the efficiency of a firm’s innovation process can often be a crucial factor for a firm’s existence and even survival. A variety of business models have been recognised in the interviews with SMEs, including:

1. Business Innovation
2. Innovation Process Development
3. Open innovation Network
4. Lead user Innovation

SME CEOs also recognise the importance of: “being innovative in order to maintain the presence in the sector and to attract the attention of private, corporate and government funds” (SME-01/30), at a national and an international level. This was strongly evident from the significance CEOs attached to being original and unique, as their main goal is to advance projects despite the shortage of financial resources and radical changes of the industry. Such strategic decisions stimulate the development or change of business models, techniques and approaches that companies adopt during the process of value creation and capture (Chesbrough, 2006). Figure 30 illustrates the different models these SMEs exercised during their innovation process, as identified in the interviews with senior executives of these firms. More precisely, CEOs and senior directors of SMEs identified a variety of strategic approaches towards innovation, as illustrated in figure 30 and described analytically in section 6.1.1.

**Figure 30: Innovation Approaches in SMEs**



From this study, firms’ innovation strategies reflect the attitudes of CEOs during the research and development activities of their firms, and this specific attitude is shaped by internal or external innovation processes, and internal or external entities. Table 20 categorises the particular models illustrated in figure 30 by positioning them with respect to their levels of innovation process and progress, both internally and externally.

**Table 20: Scope and Characteristics of Innovation Strategies in SMEs**

<b>Business Model</b>	<b>Internal Process</b>	<b>External Process</b>	<b>Internal People</b>	<b>External People</b>
Business Innovation Model		√		√
Innovation Process Development Model	√		√	
Open innovation Model	√	√	√	√
Lead-user Innovation Model	√		√	√

Table 20 illustrates the characteristics and features of the particular business models that were identified through the interviews with SMEs, with the following section 6.1.1 describing the particularities of each model based on their categorisation as Business Innovation Model, Innovation Process Development Model, Open innovation Network Model and Lead user Innovation Model.

### 6.1.1 Multi-layered Analysis: Innovation in SMEs

The variety in strategies of SMEs is evident from the interviews at a multi-layered level within the micro-meso-macro framework, within which four models can be distinguished:

Business Innovation Model:

- ❖ The business innovation model engages at a multi-layered level, as firms are closely linked with internal, corporate and industrial changes. For instance, SMEs are influenced by changes in the industry in a form of necessary and dependent relations, as they have to adopt and comply with the regulations drawn up by MHRA (Medicines and Healthcare products Regulatory Agency) and FDA (US Food and Drug Administration). Additionally, the decisions of the senior management drive the processes of events towards the development of new technologies, influenced by competition, and through collaboration with other companies and institutions. Further, the business innovation model was identified to be *“built around the improvement of the efficiency of internal productivity and technology”* (SME-01/7).

Innovation Process Development Model:

- ❖ The innovation process development model is examined through the directors' decision which delivers an innovative process development, where they identified that *“the expansion of a technology, idea or product is driven by the internal approach of the direction towards research and development”* (SME-8/20). The majority of respondent firms are driven by an innovation process development approach, through their necessary and dependent relations, to draw the attention

of venture capital funds. Particularly, when a novel compound in the area of Biopharmaceuticals can be successfully marketed, the revenues from such products can be great for the firm's investors. As VC's raise money from individuals and institutions to invest in early-stage businesses that offer high potential but high risk (Sahlman, 1990), Biopharmaceutical companies are among the businesses venture capitals fund in order to profit from great revenues. In this model, CEOs stressed the importance that *"the innovation process development is kept in-house"*(SME-10) as the necessary and dependent relations between the CEO and the CSO can lead towards the internal expansion and further development of the firm's technological process.

#### Open innovation Network Model:

- ❖ The open innovation network model can also be analysed using the multi-layered framework. The companies that employ an open innovation model are influenced by events that cause them to avoid the cost of complying with the regulatory authorities. As they transfer the test phase to other organisations and institutions through third party agreements, SMEs are saving valuable time and resources that can be invested in other projects. It is evident that the companies are diversifying their portfolios by allowing organisations, firms and institutions to work with them to form necessary and dependent relations by allowing their collaborators to allying their ideas with them. By doing so, the CEOs save valuable time in the development phase and also bringing in expertise that can take their project move forward. Clearly, necessary relations are central to the open innovation approach, as it was stressed by a CEO that *"by practicing the open innovation model we looking at a company for in-licensing, out-licensing, or working with collaborators as a circulate process"* (SME-21). Further to that, CEOs through necessary and dependent relations identified that they *"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 at the pre-clinical test phase.

Lead user Innovation Model:

- ❖ A small number of SMEs have a lead user innovation process whereby the decisions of CEOs are "*driven by necessary and dependent relations with the customers, through the development of new ideas in terms of productivity and technological advance*" (SME-29/30) Firms' take into account the necessary inputs and comments of their clients, which are either individuals or other large Biopharmaceutical firms who will utilise their products or technologies. With this approach, firms are in constant communication with their clientele and this can facilitate their needs and requirements in a more efficient way or manner.

The study also uses Nvivo, a qualitative investigation programme that examines relationships of the collected data, to analyse the interviews with CEOs and senior directors of SMEs and explore the spread of answers specific questions. With the use of Nvivo Word Tree analysis, the study can explore further the interview transcripts and identify the terms SMEs use to describe their innovation. The word tree illustrates that innovation is central in all these SME dialogues.



of the firm's technologies are on the right trajectory. To achieve their goal, CEOs implement models that **enhance**:

1. Technological development of their patents
2. Commercialisation of particular patents

In developing a successful strategy, CEOs innovate in many areas, such as the research process, their on-going development process, and their network of connections and therapeutic areas.

In determining what drives innovation in SMEs, the CEOs interviewed indicated that it is regarded as a driving force, as the term "**Innovate or die**" matches perfectly what they identified as their most critical business driver. As one CEO put it:

*"Our innovation is implemented by employing global leaders in their field, by networking with the leading companies and institutions in this area of pharmaceutical development, and by continuously striving to improve the efficiency of our innovation." (SME-02)*

This happens as CEOs are required to adopt and change their tactics to survive through the variations of the industry (Rowley, 2000, p. 325). It is important for SMEs in such competitive industries to be susceptible to changes such as the dearth of financial resources and the fierce competition on a global scale are forcing the SMEs to expand and adopt new strategic approaches.

### **6.1.2 Boundaries or Setbacks of Innovation**

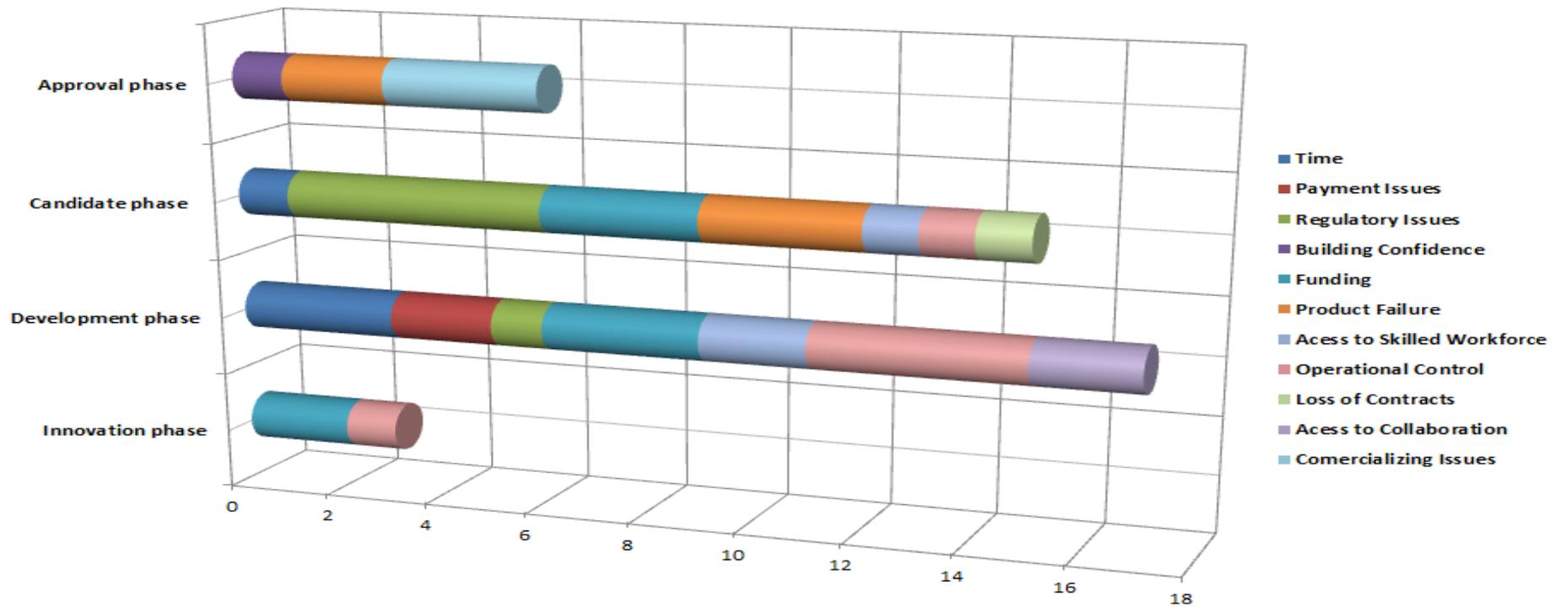
It is evident that funding, operational control, regulatory hurdles, timescales and product failure are among the most important sources of setbacks SMEs face during their innovation processes.

To examine the boundaries and setbacks SMEs face during the progress of their innovation cycle, the study clarifies the numerous **causal mechanisms** which during the implementation of the innovation plan can cause any issues and can be examined on the **multi-layered** level. When a strategic decision is applied (see figure 29), there is a possibility of creating possible issues, barriers or setbacks for a firm which the study assesses and identifies through

a critical realist approach. Through critical realism and retroductive reasoning, the study traces the actual reasons and how the specific setbacks occur. So, whether a setback actually occurs might depend on whether there is a conflict internally (CEOs vs CROs) or externally (Government vs firm; funding organisation vs firm).

The interviews indicated several issues SMEs face during each stage of the process of the development of a new molecule entity which are illustrated in detail in figure 32 and table 21. These specific issues can be traced from the initial idea progress phase, to the development phase, and then the candidate phase, and finally the drug phase.

Figure 32: Boundaries or Setbacks during the Innovation Process



**Table 21: Boundaries or Setbacks of SMEs during the Innovation Process**

	Time	Payment Issues	Regulatory Issues	Building Confidence	Funding	Product Failure	Access to Skilled Workforce	Operational Control	Loss of Contracts	Access to Collaboration	Commercialisation Issues
Idea Stage	0	0	0	0	2	0	0	1	0	0	0
Development Stage	3	2	1	0	3	0	2	4	0	2	0
Candidate Stage	1	0	5	0	3	3	1	1	1	0	0
Drug Stage	0	0	0	1	0	2	0	0	0	0	3

Figure 32 and table 21 indicate the explicit setbacks SMEs face during the progress of their innovation process, from the initial idea phase to the actual candidate phase, which were identified through the interview process with the senior executives of SMEs. Section 6.1.3 describes from a multi-layered analytical perspective the particular boundaries SMEs have to overcome to progress of their strategies.

### **6.1.3 Multi-layered Analysis: Boundaries**

From the collected interviews, numerous barriers were identified, namely:

- I. Time
- II. Payment Issues
- III. Regulatory Issues
- IV. Building Confidence
- V. Funding
- VI. Product Failure
- VII. Access to Skilled Workforce
- VIII. Operational Control
- IX. Loss of Contracts
- X. Access to Collaboration
- XI. Commercialisation Issues

The study identified that access to skilled workforce such as scientists, along with operational control and funding are the main barriers during a firms' innovation progress. This was further elucidated as the study identified that funding and mainly the shortage of resources is a barrier for any Biopharmaceutical firm, as the availability of funds for the initial investment in research and development is hard to come by. To this, CEOs stressed that the financial crisis of 2008 cash drained many firms particularly the ones listed on the stock exchange, and also early start-up firms, which is clearly evident in that funding nowadays is especially hard to come by. As the development of a new product in the Biopharmaceutical industry can take between 12 and 15 years (Vernon, Golec and Dimasi, 2010), investors nowadays are sceptical of funding Biopharmaceutical companies with such a long development cycle. The lack of operational control is evidently perceived as a weakness, as the a day to

day control concerning the contract with third parties, such as academics and PhD researchers are challenging, as it causes significant delays for the daily process of the firm.

Access to skilled workforce is an issue every firm faces, a barrier which CEOs recognised to be central to every firm in terms of not being able to employ the best possible scientists. As one of the CEOs expressed it:

*“The firm cannot possibly employ the best expert, but tries to work with top scientists and individuals with experience, but that is not always the case”*(SME-10).

Senior directors in SMEs recognise the issue and try to tackle it by increasing their productivity standards, given the fact that not all the best scientists can possibly work for a firm.

What was also stressed repeatedly by the CEOs and directors of SMEs is that the cause of losing operational control is attributed to the poor communication with academic groups and through commercial tensions with industrial groups. To overcome this, CEOs are attempting to efficiently control the internal and external resources responsible for the facilitation of innovation. Another CEO stressed that:

*“The main barriers to innovation are the poor communication with academic groups and confidentiality and commercial tensions with industrial groups.”*  
(SME-22)

Overall, CEOs indicated communication was a major barrier, which is difficult to overcome since trust and communication are cultural aspects in their mind-set. As it is vital to maintain a good communication channel during collaborative projects, CEOs in SMEs consider it to be a vital aspect during collaborative projects, thus it can be a barrier if critical channels do not communicate with each other as they should have.

Clearly, as shown in figure 32 the setbacks and barriers are often concentrated around the early development stages of a compound or a technology, which includes a time limitation, funding and payment issues, and collaboration issues as well as the operational control and loss of contracts. Presumably due

to their size and budgets, SMEs have not shifted their focus from early research towards the development phases of a new and novel technology.

Time shortage is identified to be caused because the development process of a compound takes a lot of time to go through the necessary test phases to be effective and successful.

*“As the firm is tied to some necessary expenses which are required for the development progress, it has a negative effect for other areas of the firm, as resources are quite marginal at the moment”* commented one interviewee

(SME-10)

CEOs also consistently indicated that the increasing number of tests in which compounds have to go through, cannot be avoided, and can significantly attribute to the expansion of internal issues during the development stages of the compound. What makes things harder is that several CEOs are also faced with other issues such as:

*“Accessing the requisite facilities and expertise to conduct experiments and development work is a heavy burden, and also often third party development companies charge excessive sums for development, so it can be a struggle for us to find cost effective sources.”* (SME-07)

Senior managers of SMEs indicated that CEOs who direct the companies they collaborate with, do not keep up with their necessary milestone payments, making things difficult for them, as they are funding their current projects through payments from these particular collaborative contracts.

SMEs also face several difficulties when trying to find suitable companies and institutions to collaborative with. Such issues are caused by the element that firms find it hard to locate the appropriate individuals, firms and institutions to work with. Usually, due to their limited internal resources, SMEs often find themselves struggling as operational control issues are accredited to the fact that if a mistake occurs during the research or the development process, then the firm might face serious problems as in their majority, SMEs are more than often formed around a single or small number of compounds and technologies. In terms of loss of contracts, the CEO group identified the causes to be the:

- Competition
- Industrial changes

This creates a momentum requirement which SMEs must maintain, as it is the only way to survive in such a competitive industry as the Biopharmaceutical.

Issues and challenges such as building investor and market confidence, product failures, regulatory and commercialising hurdles are also identified as playing a negative role:

- ❖ **Building confidence** has been recognised by CEOs to be *“a way to advertise our knowhow and technology, but at the same time, it can also cause tensions as it is hard to keep up with the competition.”* (SME-02)
- ❖ **Complying with the regulatory authorities** is *“a long procedure and in the same time cash draining”* (SME9), as the firm has to keep paying its internal overheads. All CEOs indicated that in terms of regulatory issues, all Biopharmaceutical firms in the sector are facing the same setbacks.
- ❖ **Product failure** is a major setback as it causes many problems such as the *“loss of funding from VC’s and other institutions”* (SME-05). As VCs and funding organisations are financing firms based on results, when a product fails, this was indicated to be the failure of a firm as a whole, as in some cases CEOs identified VCs to be their sole source of funding.
- ❖ **Commercialising issues** are seen barriers to Biopharmaceutical companies, as they might *“not have the necessary channels to successfully commercialise own products.”* (SME-05). At this point, CEOs have to rely on marketing approval, which is the pricing and the return that involves negotiations between manufacturers and authorities regarding the price of the new product and its repayment status when it reaches the final phase of marketing (Varol, Costa-i-Font and McGuire, 2010).

It is widely recognised that most issues and problems occur during the development and the candidate phase of the compound. This is often caused from the difficulty of raising funds, as when the process goes into the next level it is becoming cash drain. It has been elucidated by the CEOs that SMEs

particularly after the financial crisis of 2008, are in a tight spot as funds and resources, both private and governmental are becoming more and more difficult to come by, and the requirements of the investors have been increased significantly.

Payment issues always co-exist with funding problems. In the Biopharmaceutical industry the risk is high as if a compound fails then the vitality of the firm is at stake, whereas if it is successful then it will make a huge profit. Now regarding SMEs, the case is the same, as the mechanisms, which is primarily funding, that drive the process forward for CEOs and directors is hard to achieve. This can also be traced by the drug success rate, which during the last 10 years became very, very small as the average success rate for taking a new pharmaceutical compound through the clinical trials process and into the market is only 8% (Crafts, 2009). What is more is that regulatory hurdles are hard to overcome, particularly for SMEs with a limited number of capabilities, as it takes a lot of time to be granted and a lot of funds to carry.

Several CEOs acknowledged the issue with complying with the regulatory authorities as:

*“It takes a lot of time as well as resources to keep it on track, so it is again a resources drain, as it costs to bring that through! The costs are higher rather than complying with the regulations.”(SME-22)*

Firms also have to provide the quality and safety, as well as the effectiveness of the compound which is estimated to take around ten years for pre-clinical and clinical research (Permanand, 2006).

The study identified several barriers or setbacks CEOs face during the innovation process of the SMEs they represent, and the several aspects and stages which can delay or stop a firm's progress. Mainly, these barriers were traced both internally and externally, with CEOs and directors (entities), repeatedly stressing the overload of several specific issues. Externally, issues are traced to be caused by the difficulties the industry as a whole faces with cash flows, tight regulatory hurdles which are then transferred internally, as they are time consuming and cash draining. Additionally, the possibility of

product failure which cannot be controlled is an internal aspect, although it has been identified that new and novel ways are now introduced to SMEs that assist a compound's development. Furthermore, access to skilled individuals is what every firm always aims for, to employ the most skilled individuals. This is not always the case, as the particular individuals are driven by their personal agenda and *"these relationships have to be managed carefully."*(SME-05).

## 6.2 SMEs: Strategic Approach

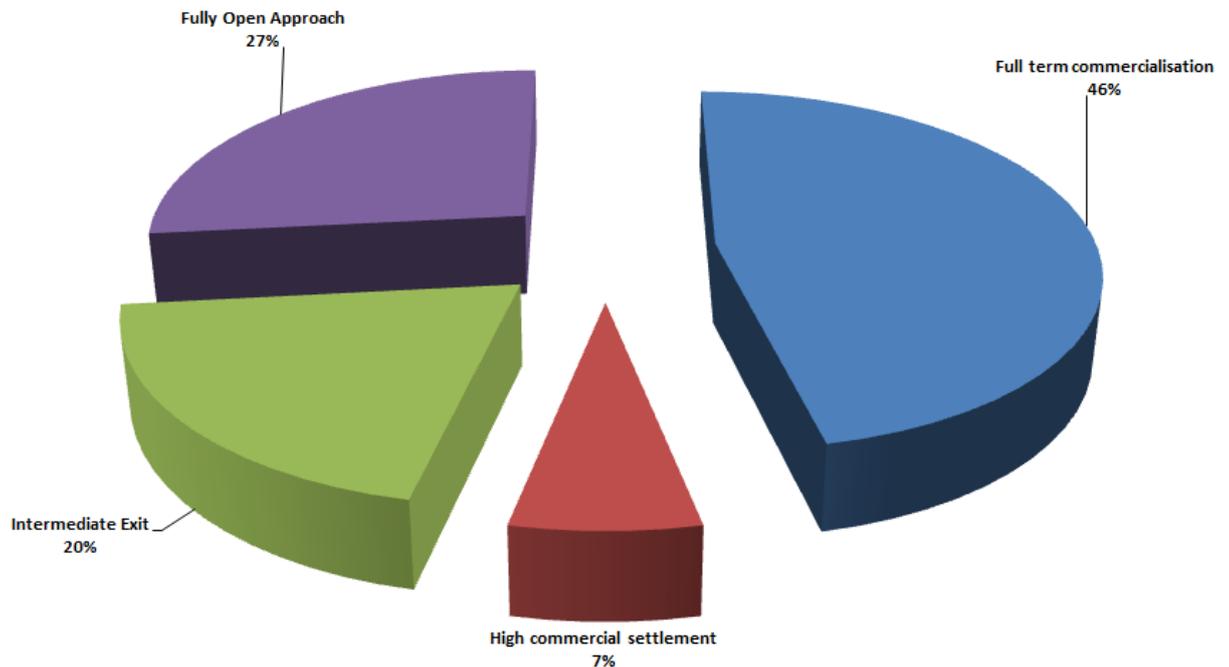
The particular section clarifies the ways in which SMEs approach their strategic processes, from a closed to an open approach and the variations in between.

The study evaluates the strategy of SMEs by tracing the **events** and **causal powers** of individuals' actions that define a firm's plan. With a **multi-layered** mode of analysis, the study traces the particular events and identifies its causal powers, as strategy has to come out of a creative process conducted under the consideration of individuals, and therefore the use of critical realism to identify the events that create these processes and with what causal powers is essential for this study.

Strategy is associated with the direction of an organisation, which in most cases has a long-term course (Johnson, Scholes and Whittington, 2008, p. 3). To validate a given firm's strategy, the study identifies the events and the powers they have which are associated in generating the senior management decisions. Moreover, a strategy is the direction and the scope of an organisation which over time achieves a lead in changing a situation through the configuration of the resources and capabilities of the firm with the aim being the fulfilment of the stakeholders' expectations (ibid). The use of critical realism will trace the **events** of the general meeting and the **causal powers** of senior management that emerge out of the strategy which is designed according to the conditions of the stakeholders. Having a clear vision of goals aligned with a competitive strategy is essential, as in the pharmaceutical industry returns on research expenditures have fallen from a return of investment of 17% in 1990 to just over 10% in 2010 (Grueber and Studt, 2011).

Figure 33 shows the various strategic approaches of SMEs the study identified, namely full term commercialisation, fully open approach, intermediate exit, and high commercial settlement.

**Figure 33: Implementation of strategy in SMEs**



### 6.2.1 Multi-layered Analysis: Strategy in SMEs

The study captured a variety of strategic approaches utilised by SMEs during the progress and process of their innovation strategies, including:

- A. Full term commercialisation
- B. Fully open approach
- C. Intermediate exit
- D. High commercial settlement

Considering each of these in more detail:

- i. The majority of firms have a full-term strategy approach to commercialisation, traced in all three levels since their approach consists of technologies that have full-term commercialisation capabilities, and are based after considering the competition and the internal capabilities of the firm. **Events** such as the success of

compound or a decision to acquire ideas are processes which are taken through careful consideration during the course of a general meeting, causing the company to continue its full-term commercialising scale approach. In doing so, the CEOs (**entities**) take into consideration the firm's technological strengths and weaknesses (**causal power**) and evaluates the scientific capabilities and potential revenues (**mechanisms**). Moreover the term, *“if a business model is working very well it will continue to be our model” (SME-09)*, describes what several CEOs indicated as a part of their strategy.

- ii. The study traces the approaches that consist of the intermediate exit and the high commercial settlement duration. By having an intermediate approach, the CEOs manage (**causal powers**) to have exit strategies for investors which in most cases are venture capitals. So the approach is: *“to use the technology we provide to the product of a big firm in order to generate revenues” (SME-07)*, therefore the management of firms are on the search to be acquired (**event**) within 3-5 years' time.
- iii. A small number of SMEs are based on a high commercial plan, which is focused on their customer needs, and can be described as a lead user innovation plan. This means that there is a direct link between the customer and the firm, as *“the idea is developed with the customer and we pretty much forward it to another company” (SME-29)*, and also in terms of product development and marketing of services which the management considers vital (**causal powers**).
- iv. The fully open strategy model is explored on all three levels, as it consists of methods that have a long-term application with the adoption new ideas, and in addition, it also consists of an intermediate approach based on a strong internal position with an open eye for embracing new technologies and also a high commercialising strategy that might change the structure of the firm particularly when a new technique arises. On these grounds, evaluating the market and the clinical drivers, and also constantly looking for solutions to problems, are the key characteristics of an open strategy approach as it requires innovative solutions for particular issues. The senior management recognise *“the fact that to thrive in the Biopharmaceutical industry you must have a strong position in terms of the research and development and at*

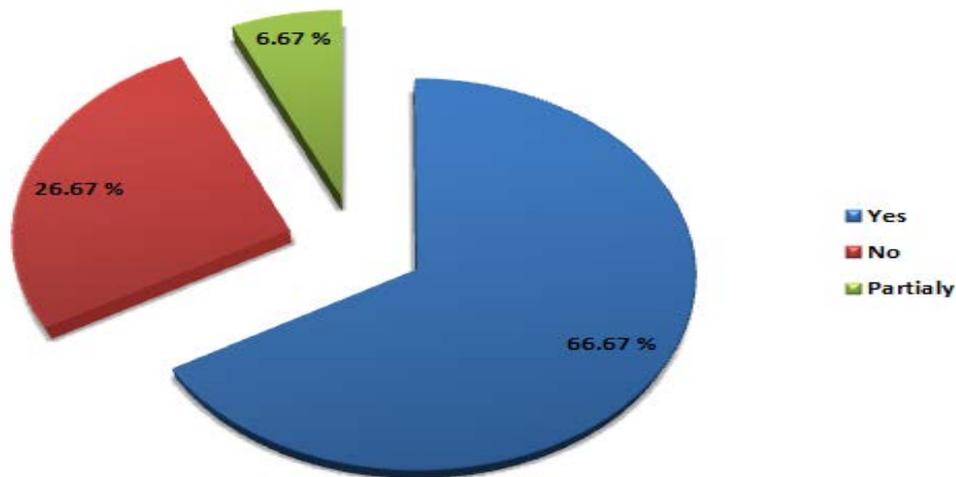
*the same time they have to be aware that many of the issues the company face” (SME-23).* Such issues can be tackled by changing an aspect of the development process, such as technological advantage equipment, a new way of analysing compounds or various other industrial changes. At the same time, some firms are open to changes and alterations of their strategies as long as they are financially successful (**event**). In addition to that, firms are always on the lookout to acquire innovative products which can be combined with their core activities (**events**) and build up cash steady flows (**causal powers**).

The analysis of the strategic plans of the SMEs indicated they value their process and keep it under careful consideration. This can be traced by the diversity and variation of strategies CEOs (**entities**) adopt, which in most cases have full commercialising duration, and can be associated with a Business Innovation Model. On the intermediate term SMEs are associated with the Innovation Process Development Model, and the highly commercial approach with the Lead user Innovation Model. The fully open approach is associated with the Open innovation Network Model as it is influenced by many parameters.

### **6.3 In-source Approach in SMEs**

In a way to identify the level of openness, the study accesses the in-sourcing capabilities of SMEs, which are vital signs in identifying the level of openness in firms. The following figure describes the likelihood of CEOs in insourcing capabilities that exist outside the boundaries of their firms.

Figure 34: Susceptible to In-source?



### 6.3.1 Multi-layered Analysis: In-sourcing in SMEs

Regarding in-sourcing, although the majority of SMEs engagement is in outside sourced technologies (73%), a significant amount of firms (27%) prefers to develop through their in-house capabilities. SMEs insource ideas and technologies from outside the firm, mainly because their capabilities do not allow them to grow beyond a point or because they realise that ideas and technologies also exist outside the firm. It is vital for firms to seek out for assistance as in many cases technological improvement comes from outside, as the size of the firm is small therefore it is appropriate to out-source their lab work to either partners or business collaborators. As one CEO indicated, a major driving force of in-sourcing is usually:

*“The lack of internal competence, as the improvement of the firm’s efficiency has to be done by using equipment from an external source or associate, rather than purchasing the particular equipment by ourselves” (SME-06)*

CEOs in firms who adopt in-sourcing approaches identified that external knowledge and equipment is necessary as their firm do not have the resources and funds to pursue specific advances with internal capabilities.

In addition to this, working with universities brings ideas into a project as the research and development happens outside of the firm, therefore, the firm can *“allocate the time and resources into another project and effectively work in*

*two projects at the same time*" (SME-23). This kind of in-sourcing has been characterised by a CEO as:

*"A form of know-how acquisition, as external cooperation is the key to the innovation process" (SME-06)*

Clearly, for some SMEs, in-sourcing is a form of technological acquisition rather than internal development, as not only does it save funds that can be allocated into other projects, but it is also a way of bringing in technology faster and better than the internal pace. On the other hand though, several firms (27%) prefer to keep the research and development in-house, as they are reluctant to lose control of their technology as it is uncertain what outcomes will be provided. This happens as SMEs do not take the risk to acquire similar or different technologies as it might deteriorate the company's internal processes.

Another common form of collaboration and co-development is out-sourcing, meaning that technological resources can be developed outside the boundaries of the firm. To assess where out-sourcing activities and techniques are used the study evaluates if and how they are exercised.

## **6.4 Collaborations and Networking in SMEs**

The nature of collaborations is explored to identify if and when open collaborative projects are used by SMEs.

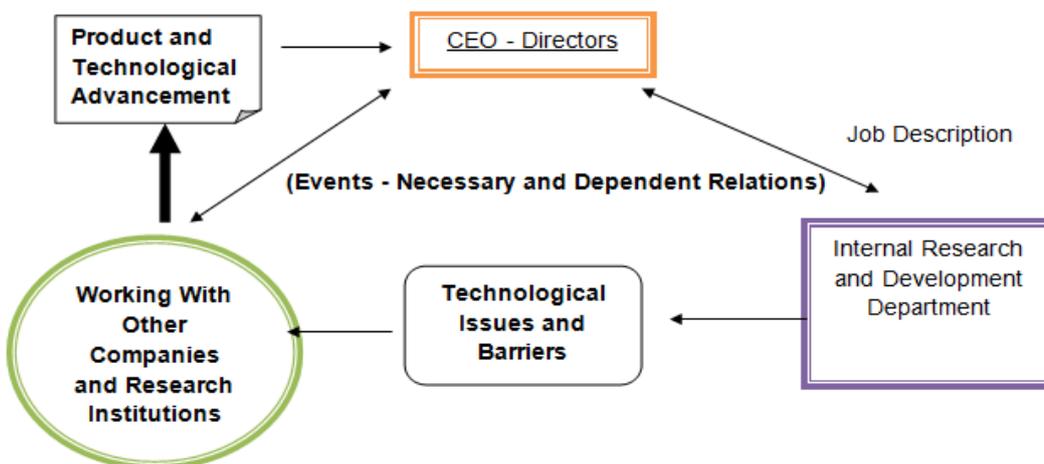
Collaborations are seen as an efficient way of accessing additional or complementary resources that can speed up the exploitation in an area in business (Teece, 1986; Arora and Gambardella, 1990). Chesbrough (2003) argues that collaborations are a form of in-bound innovation as they can reduce the burden on innovating companies by creating opportunities to spread out risks (De Jong et al, 2008, p. 6). The Biopharmaceutical industry has been seen as an example of technological collaboration and competition (Arora et al, 2004) as firms are increasingly dependent on external sources of innovation through inter-organisational network relationships (Perkmann and Walsh, 2007, p. 259). In pharmaceuticals and biotechnology, the interactions between knowledge, technology, institutions and country-specific factors have

formed the evolution of the industry (Malerba, 2006, p. 24). The study evaluates the level of collaboration to validate how important collaborations are for SMEs and where open innovation has an impact on these collaborative actions.

Business relationships in firm are seen as social structures, which like other social structures, might change over time (Bhaskar, 1978). Consequently the use of critical realism will help in building a research analysis based on a thorough investigation of the **empirical** level. Consequently, current situations and events in which the senior management of firms is experiencing during their process are business activities and issues are developed in **actual**. To evaluate the level of collaboration within the Biopharmaceutical SMEs the study identifies how the research and development of firms is carried out in-house and why.

To understand how a collaborative model is expressed the study assesses the relationship between the senior management of firms that have certain causal powers and liabilities that can shape a particular approach towards collaborating or not. Through the use of retroductive reasoning, the study traces the specific reasons of why and how collaborative activities occur and the reason that produced them. Specifically, figure 35 indicates the process in which collaboration as a strategy can be adopted from a firm and how that mechanism works (Sayer, 1992, p. 11)

**Figure 35: Structure of Collaborations Process in SMEs**



Adopted from: Sayer 1992, p. 93

The study captures the progression of SMEs during the development of their collaborations, and categorises them based on the multi-layered approach.

### 6.4.1 Multi-layered Analysis: Networks and Collaborations

By employing a multi-layered related approach, the analysis identifies the **events** that produce the **necessary conditions** to closely work in collaboration with various individuals, firms, institutions or research organisations. The **necessary and dependent relations** of the CEOs and the senior management can assist the firm in deciding upon the best collaborative model.

By assessing the likelihood in which firms engage in a collaborative programme or a network creation, the study evaluates whether such strategies that occur allow firms to expand their technologies and value, and the relation of such models compared to open innovation approaches. To clarify the reasons of how such practices are used by firms and their motives, the study uses **critical realism** (Sayer, 1992) to trace the **events** and the **necessary and dependent relations**, as innovation is now being executed within networks of firms, rather than within a single organisation (Chesbrough, 2006).

Figure 36: Micro-Meso-Macro Level of Collaborations in SMEs

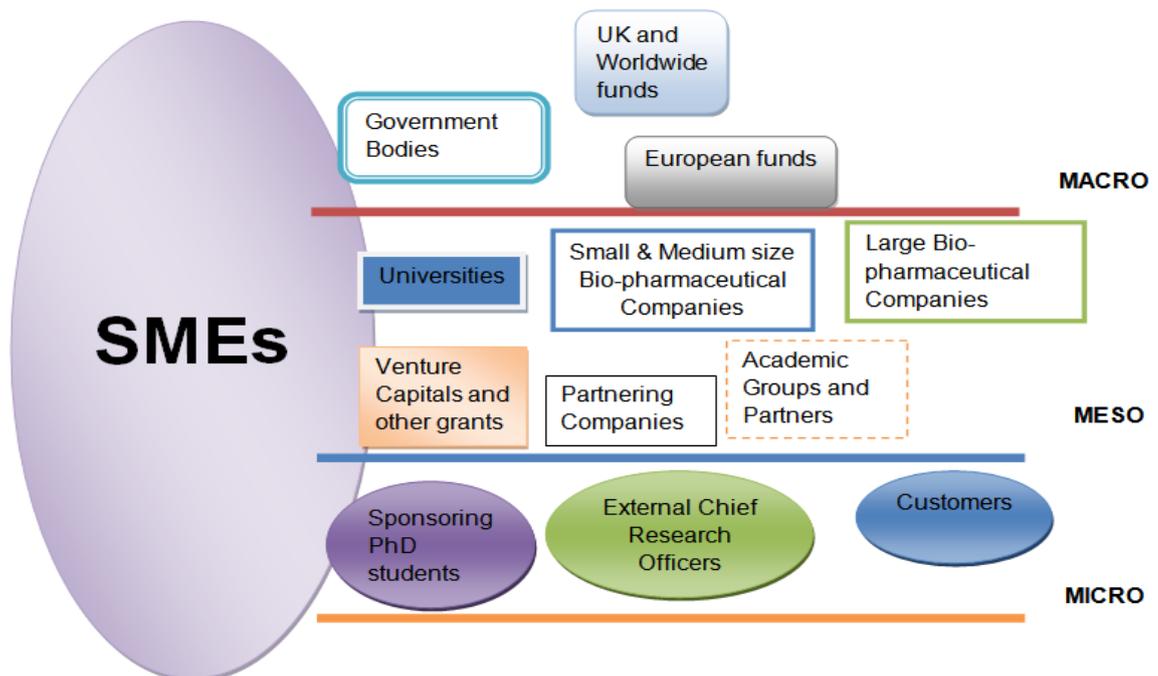


Figure 36 explicitly describes the nature of collaborations within SMEs, varying from PhD candidates and customers at the micro level, to academic institutions, large firms, VCs and various large Biopharmaceutical firms in the meso, and government and international bodies in the macro. The study with the use of a multi-layered approach can identify and explain the several collaborative approaches and methods SMEs exercise during the application of their innovation strategies.

From the analysis, the study can clearly identify that there is a big variation of collaborations in all three levels of analysis, categorised:

- Government bodies and organisations on the macro
- Partnering companies on the meso
- Customers on the micro

The following section conceptualises the particular collaborative approach of SMEs based on a multi-layered approach.

- i. On the **macro** level of analysis, the firms have a close cooperation with government bodies such as the Technology Strategy Board for joint funding *events* such as the Nanoscale Technology Enabled Healthcare<sup>14</sup>, and the Health Protection Agency which through *necessary* and *dependent relations* provide national, regional and local health protection services.
- ii. The **meso** level comprises several SMEs and large Biopharmaceutical companies, various other institutions including universities and academic groups. Soedifically, Not surprisingly collaborations exists with academic institutions, as university and industry relationships have been identified as a growing phenomenon by scholars for more than 30 years, as the process of technology transfer from research universities to private firms is expanding more and more (Rogers, 1986: 169). Moreover, venture capital firms and other grand institutions are involved

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<sup>14</sup><http://www.innovateuk.org/content/competition-announcements/nanoscale-technology-enabled-healthcare.ashx>

at the meso level and can be analysed by identifying the *necessary* and *dependent relations* of CEOs.

- iii. The **micro** level consists of the *necessary* and *dependent relations* firms have with various individuals, such as external research officers and customers.

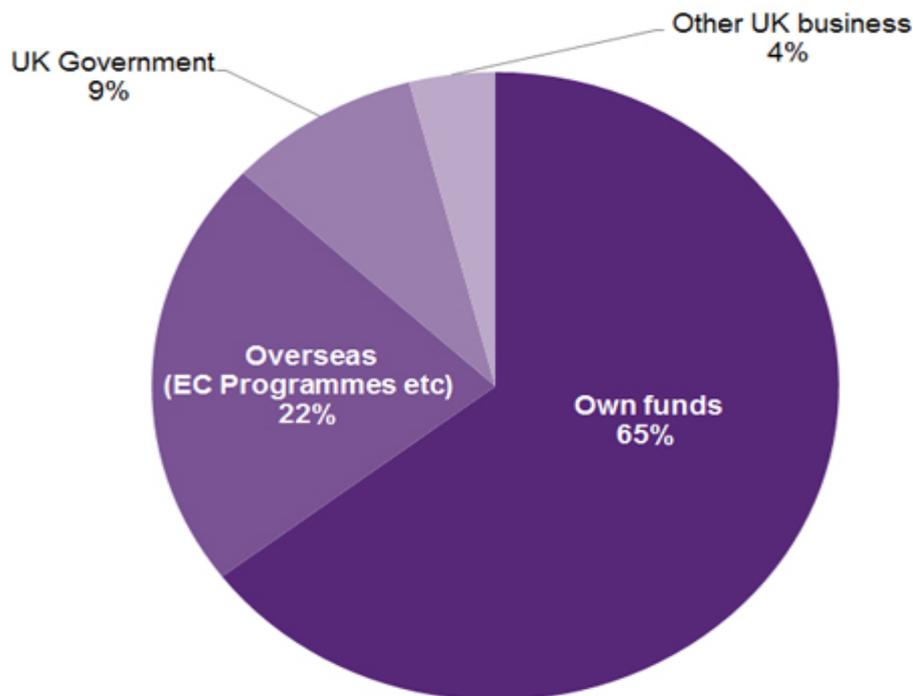
The study also indicates that the majority of firms engage themselves in several collaboration activities, ranging from:

- Technological advance
- Revenue through joint programmes
- Joint contacts with various firms and institutions
- Developing a good reputation

On the other hand, a small number of firms do not engage in any form of collaboration as they believe in the notion that they are “experts in the field” or that the traditional model that is currently in use works just fine.

As figure 36 illustrates, collaborations occur on a **multi-layered** level, and during the different stages of a firm’s process, such as the research and the development of a new technology or novelty. The founding and financial support the SMEs receive from third parties such as grants, both on a national and international level is seen as a vital and important aspect for the majority of the participant firms. Through critical realism, the study traces the *events* such as the Pharma Summit and the Royal Pharmaceutical Society annual conference, which bring firms and institutions together with the hope of expanding the pharmaceutical research and development on a national and international level. Figure 37 clearly illustrates the distribution of funding in the pharmaceutical industry, which mainly consist of personal funding and various overseas programmes and governmental funds, this indicates the difficulties firms face in securing their funding as the majority of their resources comes from own funds.

Figure 37: Sources of funds for pharmaceutical business in the UK

Source: ABPI<sup>15</sup>

Combining internal technology with external sources to generate something new is among the most common reasons why CEOs in SMEs have engaged their firms in such activities, to create *events* in which their firm will gain a technological advantage. Through these particular events, the development of new techniques and new drugs contributes to the creditability of firms', which were identified to be used as leverage in future collaborative programmes. Moreover, the study traced that the particular SMEs exploit certain areas which cannot be covered internally, and are seen as a driving force or a *mechanism* that creates particular collaborative *events* and programmes with various institutions and groups. It has been identified by the interviews that when mutual development plans are implemented, they improve in-house processes and assist the firm in expanding its knowledge in specific areas. In addition, these collaborative actions are considered as a mechanism that moves the company's technology forward and is a good way of advertising, as well as captivating ideas from the collaborating partners and in that order develop

<sup>15</sup> <http://www.abpi.org.uk/industry-info/knowledge-ub/randd/Pages/funding.aspx>

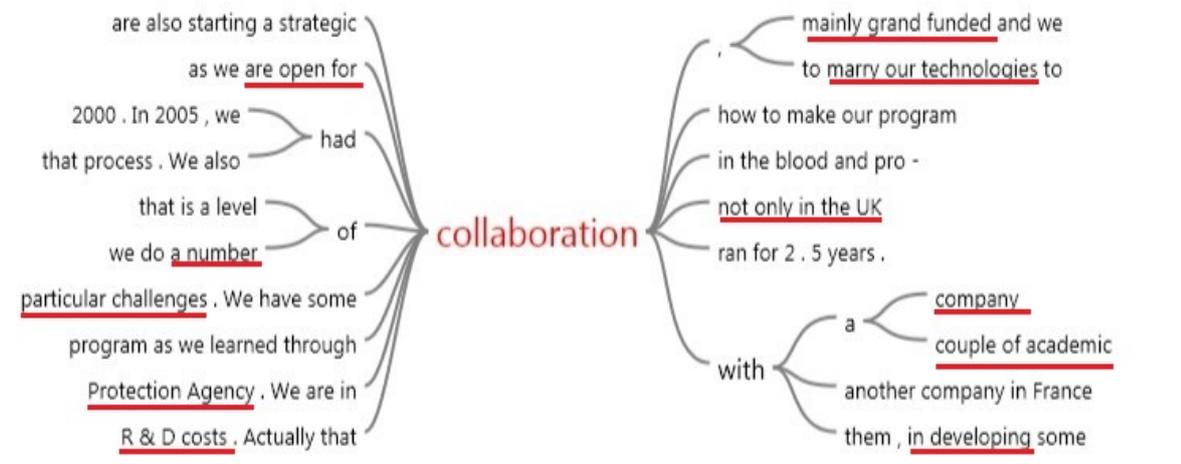
them further. At this point, the role of venture capitalists was praised with importance as they have a stake in firms, which is their investment and through their *dependent relations* push things forward when there is the need to do so.

On the other hand, some firms do not engage in any collaborative programmes as the ownership of the IP, which is of vital importance is not shared with other companies. Moreover, a number of firms consider that an internal development is better, as external collaboration might endanger the firm and lead to the wrong decisions regarding investing in a technology which is not tailored to the firm's specifications.

The shortage of expertise especially in such innovative sectors, affect the firm directly in terms of collaboration and joint development, as through their *necessary* and *dependent relations*, CEOs try to contract the most suitable professionals to work with. As the principal responsibility of the CEOs for the activities of a company (Downes and Goodman, 1998, p. 93) such as to optimise the firms' revenues and technologies, their background and connections in the industry gives the firm the necessary tools to do so. It has been identified that collaborations have a direct effect on enhancing a firms' intellectual property which otherwise would not be possible. Through collaborative programmes, firms' leverage their technologies and resources and therefore have more time to practice different innovations and technologies.

In another Nvivo Word Tree analysis, the study explores and identifies several aspects and reasons why firms engage in collaborative agreements, based on the interviews of CEOs.

Figure 38: Nvivo Word Tree – Collaboration in SMEs



More specifically, SMEs have been identified that are open for collaborations not only in the UK, but also with other companies through EU-funded programmes and other research initiatives (NICEATM, SEURAT etc.). This can be traced by events such as the “SEURAT” which has been designed by the European Commission to be responsible for the development of non-animal testing methods. In addition, the Health Protection Agency creates several events in protecting the public from infectious diseases or radiation hazards, and from new and emerging threats, including new strains of viruses or bioterrorist attacks<sup>16</sup>.

Due to increasing R&D costs, CEOs have come to realise that the only way of overcoming technological obstacles is by allowing a “*co-development*” process to take place that will allow the firm to relocate its resources. In doing so, the CEOs and senior directors are trying to create the *necessary* and *dependent relations* with other institutions to achieve the development of a new treatment, the advance of their technology and the placement of their products. Furthermore, the need to collaborate due to shortage of knowhow and the fact that several researchers in the field have *causal powers* which can improve a firm’s position is an important factor that CEOs take into consideration in deciding upon working with external staff.

<sup>16</sup> Health Protection Agency - <http://www.hpa.org.uk/EventsProfessionalTraining/>  
148

This does not necessarily mean that even though the majority of SMEs (90%) engage in collaborative networks and agreements, they are utilising open innovation strategies. It has been identified that the main reasons in which SMEs are prone to collaborate lies in the fact that through collaborations companies create awareness by establishing a good reputation. This is also supported by De Jong et al (2008, p. 18), as they argued that innovation collaboration in SMEs is a long lasting tradition, as small and medium sized companies lack the resources to fund innovations by themselves, and at the same time cannot maintain large innovation portfolios that can assist them in spreading their risks (Nooteboom, 1994; Vossen, 1988).

Furthermore, the UK government through the NHS creates projects such as the collaborative commissioning between clinical commissioning groups, and the TSB through funded collaborative research and development (R&D) projects. Collaborating is a way of bringing different perspective for specific problems, without spending large sums of resources into individual projects.

## **6.5 Evaluation of Networks in SMEs**

In collaborating with various external groups, institutions and individuals the firm is developing some sort of network which allows the firm to access resources and expertise.

To evaluate the development of a network within the Biopharmaceutical firms the study addresses where such activities exist and with whom. Based on retroductive reasoning, the study identifies as figure 38 describes, the specific reasons of why and how networks are formed, and with which particular individuals or organisations.

### **6.5.1 Multi-layered Analysis: Evaluation of Networks**

Collaborations exist on various levels and with various groups, corporations and individuals.

It has been advocated that scientific results brought from academic institutions increase sales, higher research productivity and patenting activity for enterprises particularly in biotechnology (Cohen et al, 1998). Without these

inputs of academic research many innovations could not have been recognised or would have originated considerably late. Ever more, university research projects are partly funded by private enterprises to benefit from knowledge spill-overs by facilitating the exchange of ideas, promoting creativity and innovation (Colyvas et al, 2002; Carilo, 2001). More specifically, the study examined:

1. The **necessary and dependent relations** that exist between the firms and various academic groups as well as customers, create a network of knowledge and technological expansion.
2. Similarly, the **necessary and dependent relations** of CEOs form connections with various companies, large, medium or small in size and also universities.
3. In the same way, the **necessary and dependent relations** that exist in SMEs assist in securing funding, assisting in legislation dossiers on a national and international level, as well as national health organisations and various technological boards that work in a supportive and guiding body.

The CEOs also argued that internal firm considerations are more important than external (environmental) factors, in influencing the distribution of R&D which is controlled by medium and large multi-site UK pharmaceutical companies with the argument supporting the internal structure of companies (Howells, 1984). Good links between R&D and other activities of a firm played a major, if not dominant factor in the location of R&D units (ibid). Arguably, a firm's internal development as access approach involves obtaining the needed resources and capabilities from multiple sources except the incumbent consortium. While the needed resources and capabilities may be sourced from inside the firm's boundary, firms commonly seek resources from outside, despite a tendency toward local search (March and Simon, 1958; Nelson and Winter, 1982) and the costs and challenges associated with transfer (Arrow, 1969; Rogers, 1983; Szulanski, 1996; Teece, 1977). Inside its boundary, a firm may source from different divisions and across functional departments (Lee and Lieberman, 2010). Lee and Lieberman, (2010) agreed that many innovations fail to achieve adequate returns on their investment (Mansfield,

1969). Moreover, new products and services often take a long time to develop, and the amount of market share captured through internal development may be smaller than what can be realised through acquiring an incumbent.

The study captured and identified the reasons why firms engage themselves in a collaborative agreement with various partners, as CEOs indicated that:

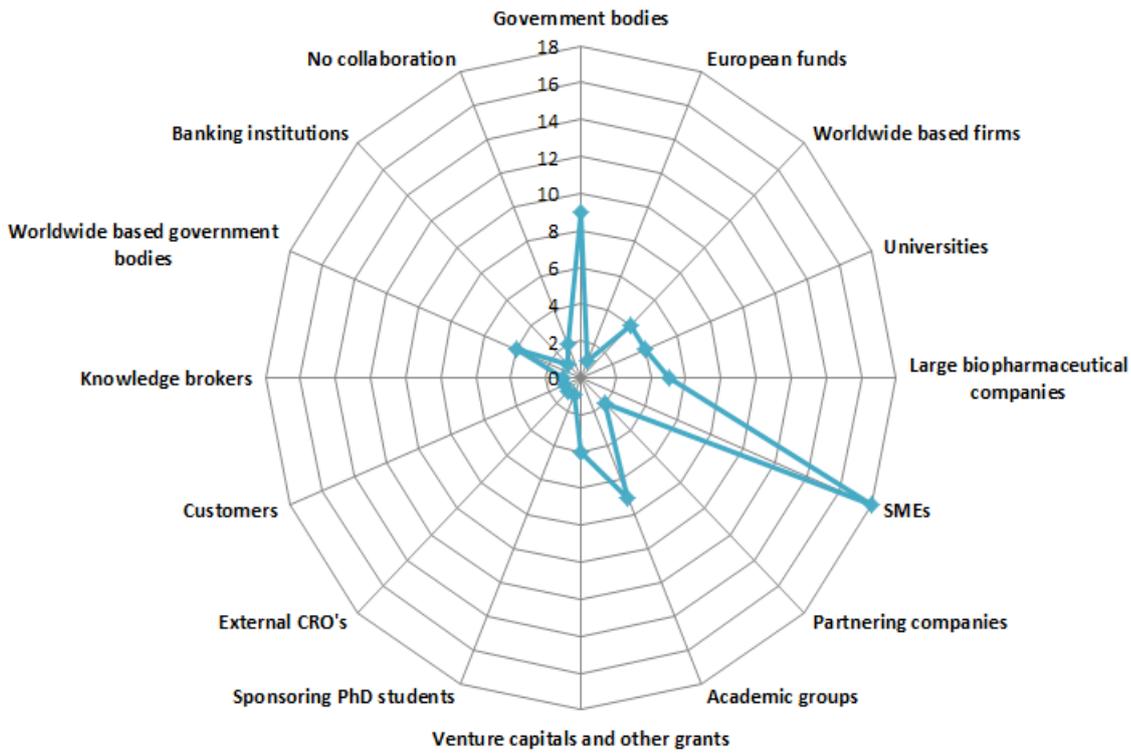
- A. *“External collaborations are vital for the firm, since they are a source of new technological advance as well as a foundation of the expansion of in-house capabilities.” (SME-23)*
- B. *“The shortage of in-house capabilities is a driving force to look outside the boundaries of the firm for further research and development.” (SME-27).*

From a **multi-layered** perspective, collaborative programmes have been identified by CEOs to be an important aspect that *“enhances a firm’s credibility to the market, and it makes it easier for funding bodies to invest in a company that has a reputation of successful collaborative programmes.”(SME-05)*

Not surprisingly though, although CEOs are pro-active in working with external associates, a small number of them are sceptical about doing so.

It has been identified through the interviews that a small percentage of firms (9% - 10%) insist in in-house development, due to efficient capacities as well as being concerned that in case of sharing the firm might lose its assets. This is mainly the fear of trust, as there is always the possibility of potential unethical activities in terms of copying and reverse engineering the firm’s technologies.

**Figure 39: Distribution of Collaborations in SMEs**



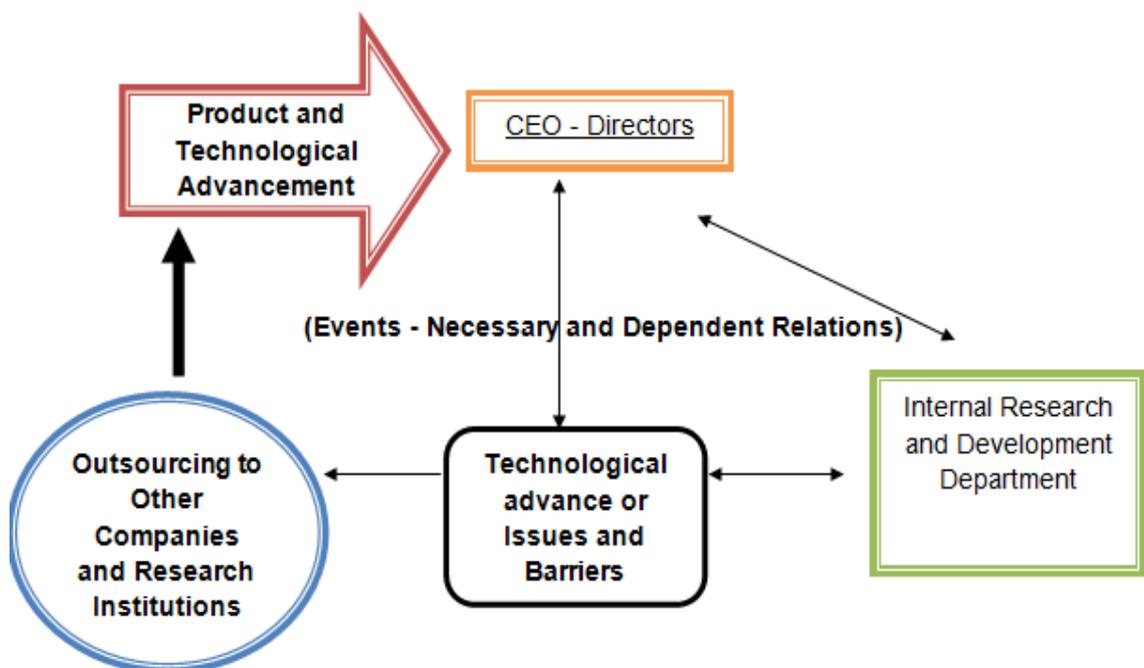
Clearly as figure 39 shows, CEOs identified that SMEs are keen on working with various academic groups and partners, as it has been acknowledged as a main source of technological inputs, either from collaborative projects or personal contacts through necessary and contingent relations with various academics. A significant number of SMEs (22%) are working with other firms from the same area which can lead to successful collaborative inventions, either with competitors or various reputable firms in the area. CEOs have been pro-active in utilising technological inputs from PhD candidates which can save a significant amount of resources and time. A substantial proportion of SMEs engage themselves in collaborations not only at a national level but at an international level too, to draw attention as a form of advertisement expansion, market enlargement, and captivate potential know-how, or even to leverage their investment portfolio.

Research and development is among the most important aspects of Biopharmaceutical companies, and as one CEO put it *“the existence and survival of the firm depends on research for new and existing methods which will therefore lead to the development of a new compound or the expansion of*

*the existing one*" (CEO-01). Decisions regarding which technical capacities to develop internally and which to access through collaborative and contractual links with external sources may affect the firm's long-term viability in the new technological environment (Pisano, 1990, p. 153). Thus, the use of critical realism will support in building a research analysis based on an investigation of the **empirical** level, such as necessary and contingent relations and events which the senior management of firms are experiencing during the process, in which the **real** business activities and concerns are developed to **actual**.

In collaborating with various individuals, external groups and institutions firms usually trend to acquire or insource technologies. To assess where in-source activities and techniques are used the study evaluates if and how they are exercised, as figure 40 illustrates.

Figure 40: Structure of R&D strategy in SMEs



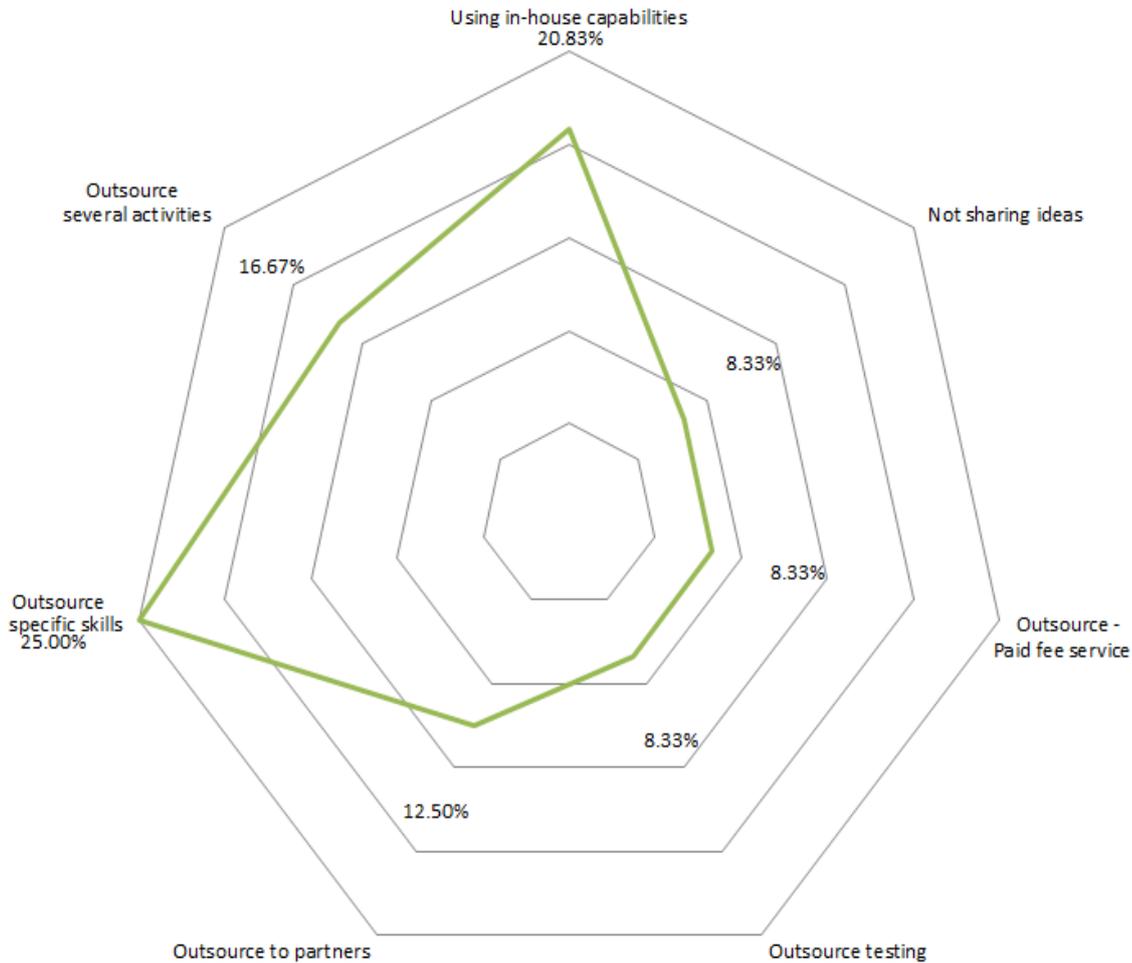
Adopted from: Sayer 1992, p. 93

## 6.6 Out-source Approach in SMEs

There is a strong tendency in some SMEs to out-source technologies but at the same time a significant number are keeping them in-house.

This is supported by the data in figure 41 that illustrates the reasons for which CEOs in SMEs consider out-sourcing during their process strategies, and the possibility of outsourcing parts of their process to external sources, which is described in detail in section 6.6.1.

**Figure 41: Out-source Strategy in SMEs**



### 6.6.1 Multi-layered Analysis: Out-sourcing in SMEs

On the **multi-layered** level, as figure 41 indicates, the majority of CEOs (71%) at some point have out-sourced a part or a whole section of their technological process by a variety of means:

- I. Dynamic Out-source Strategy
- II. Outsource on Paid fee service
- III. Outsource specific testing

- IV. Outsource to partners
- V. Outsource specific skills
- VI. Outsource several activities

In doing so, the CEOs advocated that they are responsible for facilitating and promoting the projects and processes of the firm to out-side contractors, partners and research organisations.

- A number of firms (8%) subcontract their technologies to universities and precisely to PhD candidates who provide the necessary inputs on a paid fee service to the university, in the form of scholarships and sponsorships.

Based on the above, CEOs indicated that building necessary relations with scientists and academic groups from universities can effectively assist the firm to out-source and diversify particular activities.

- A number of firms tend to hire people that have the necessary expertise and power to strengthen their position by creating networks with various other firms through their expertise.

This means that the particular people (CEOs) create the necessary and dependent relations with various firms and institutions through networking. In addition to that, some firms recruit consultants to assist them with the particular partnering companies.

- At least half of SMEs outsource their testing, various skills and activities to specialists and various labs as they do not have the capabilities or power to do so in-house.

These forms of outsourcing, take place through effecting collaborations by creating availability to particular recipients which is done through a pay to fee service.

- A particular way of creating awareness is by attending several conferences which gives CEOs the space to create the necessary and dependant relations with other firms and institutions.

On that, they can attract several firms keen on publishing their work and through that they further attract attention from other individuals, firms and organisations who work in the same area. By publishing their data results, CEOs secure that the particular publication is their own work, and at the same time avoid unnecessary expenses such as primary IP investment.

- o The Seventh Framework programme was identified to be a way in which SMEs outsource their technologies under the European Union's strategy which secures confidentiality and at the same time has a double effect as it increases the reputation of the participant firms.

The particular approach is seen as a source in which the CEOs can establish a good reputation, as through such programmes they can be identified as being a part of a successful group. Moreover, CEOs are seeing the FP7 as a reason to diversify internal projects in collaboration with out-side partners.

- o A small amount of firms (12.5%) do outsource their activities to a partnering company as they have already tailored an agreement with them.

A significant factor that drives CEOs to outsource their technologies, is the access other firms and institutions have in their patents from public records, by matching their technologies together. SMEs are contracting the further development of their novelties to big manufacturing organisations or partner with pharmaceutical companies to keep the costs to a minimum.

On the other hand, nearly a third of the firms (29%) prefer to keep their capabilities in-house, and have been identified based on the CEOs responses.

- A. "Prefer to improve internal capabilities rather than out-sourcing them." (SME-10)
- B. "Believe that specialist is employed in-house." (SME-20)

In this respect, CEOs identified that due to their size, firms are usually developed around a single or a few technologies, and the last thing they want is to share it with others. Due to the fact that they consider themselves as the experts, several CEOs do not wish to jeopardise quality over cost therefore

they are not keen in outsourcing or sharing their technologies. Consequently nothing comes in or goes out of the firm, as the senior managers do not want to share their novelties.

The next section 6.7 describes the research and development capabilities of SMEs, how they are exercised and why it is important.

## **6.7 Research and Development Capabilities**

The study observed that the capabilities of SMEs vary from completely closed in-house to fully open, with several SMEs being in the middle.

Considering the likelihood that firms engage in an outsource technique or a network creation, the study evaluates where such strategies occur compared to open innovation strategies. To clarify the reasons of how such practices are used by firms and their motives the study uses critical realism (Sayer, 1992) to trace the events and the necessary and dependent relations, as innovation is now being executed within networks of firms, rather than within a single organisation (Chesbrough, 2006). With the use of critical realism, the study uses retroductive reasoning to identify the individuals responsible for the production and facilitation of a firm's R&D capabilities.

### **6.7.1 Multi-layered Analysis: Research and Development in SMEs**

The CEOs have indicated that their firms have created an internal environment in which the research and development of their technologies is controlled in-house with the application of the mechanisms and causal powers of the scientific team, which is in many cases the CEOs themselves. Based on that, the study identified that the causal powers of CEOs are responsible in most cases in developing the internal capabilities of the SME as follows:

- CEOs try to capture and learn new techniques to expand the efficiency of their internal development, by hiring skilful individuals.
- Due to the limited size (mechanism) of the firms', CEOs (causal powers) are on the search to improve existing processes (events) rather than out or in source any aspect of their process.

On the other hand now, the vast majority of CEOs tend to prefer a hybrid form of research and development process, which is sometimes fully carried out outside the firm. CEOs indicate that they out-source their R&D capabilities as follows:

- 1) PhD candidates to provide the necessary experiments rather than investing in creating the necessary sections within the firm.
- 2) Several industry professionals exist in the industry but not tied to the firm, thus firms should and must be alert of their presence. This means that CEOs and CSOs build the necessary relations with various professionals that will be contacted in due course.
- 3) A number of SMEs keep the innovative chemistry of a compound in-house and out-source the clinical trial test in the form of hybrid collaborative R&D, as internal capabilities are not adequate enough.
- 4) A small number of SMEs out-source their work instead of employing people which has a direct cost implication for the firm.
- 5) SMEs are able to carry out the initial research in-house and employ their necessary and dependant relations to out-source specific skills, such as the testing or further development when their skills are short.
- 6) Universities with their laboratories (causal powers) are considered by CEOs when they wish to further develop their novelties, as they are seen as sources of technological expansion with limited cost implication.

This trend happens very often as SMEs do not have the capabilities to carry out clinical trials therefore they pass them to pharmaceutical or biochemist firms for further development. In a particular case, a CEO argued that *“it is likely to out-source specific activities overseas through the dependent relations with external associates, as the development of a technology in the UK can be very expensive”* (SME-22). On that, some firms identified that searching overseas can lead to a successful match as many countries worldwide use innovative technologies and techniques. More specifically, as a CEO put it. *“when we reach the point where our capabilities are a bit short for the ongoing process, we actively and openly seek out for large Biopharmaceuticals to acquire and develop it further. It happened in a few occasions”* (SME-24)

The success of the pharmaceutical and biotechnology industries, depends on the specification and enforcement of private rights which secures the market for their products and technologies (Maskus, 2000, p. x), therefore intellectual property is a vital part of their business. The open innovation concept stresses the importance of using a wide range of sources for a firm's innovation activities while at the same time using novel methods to exploit a firm's resulting intellectual property (Chesbrough, 2003a). In an open innovation strategy, a firm can utilise its intellectual property rights and formulate tools to manage the specific openness (Lee et al, 2010). A firm can utilise its unused intellectual property, called outbound open innovation, through selling patents, direct licensing, or on intermediary markets (Arora et al, 2001; Chesbrough, 2003a; Chesbrough, 2007; Schroll and Mild, 2012, p. 478).

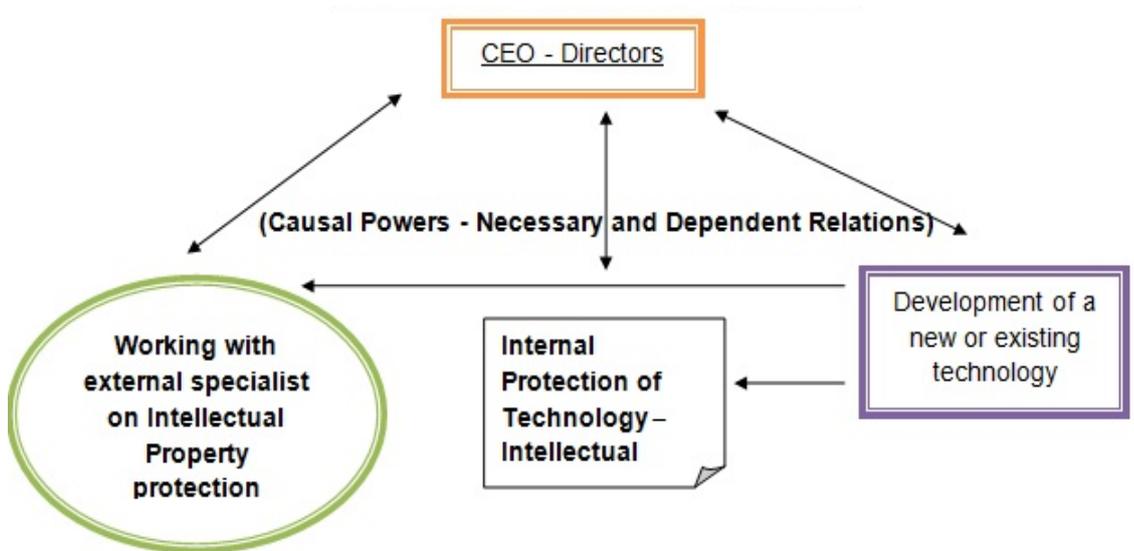
The next section 6.8, the study examines the application of intellectual property in Biopharmaceutical SMEs, as evidently nowadays pharmaceutical markets in a worldwide context are becoming more regulated by patent systems (Drahos, 2004, p. 402).

## **6.8 Intellectual Property approach**

SMEs have a critical view regarding the development of their property portfolio, and are very protective towards their IP.

To understand how intellectual property is expressed, the study looks at the relationship between the senior management (chairman or board of directors) of SMEs and the CEOs (Chief Executive Officers) that have certain causal powers and liabilities over the research and development of a technology/compound. Based on a critical realist approach, the following figure 42 identifies the process and relationships in which intellectual property approach is exercised by a firm and how that mechanism works (Sayer, 1992, p. 11). With the use of retroductive reasoning, the study identifies how the individuals responsible affect the intellectual capabilities of SMEs.

Figure 42: Intellectual Property Structure in SMEs

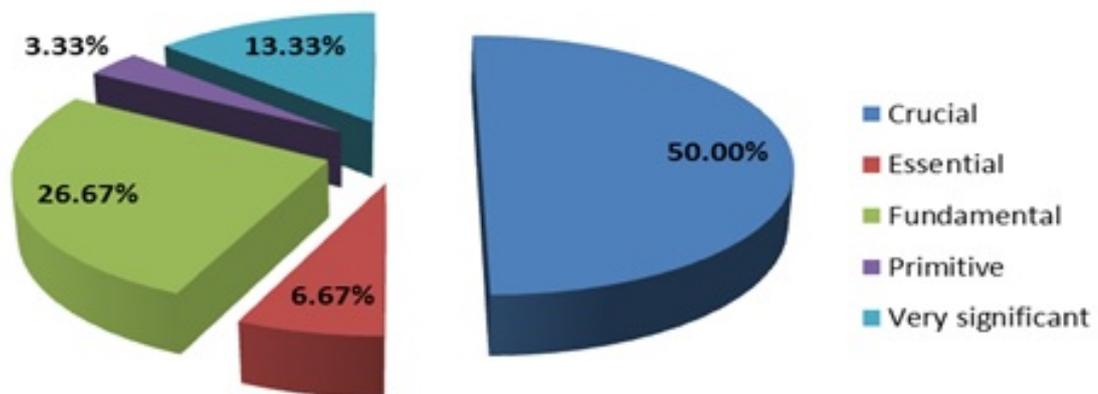


Adopted from: Sayer 1992, p. 93

To assess how important intellectual property is for SMEs the study evaluated the level of significance IP has for Biopharmaceutical SMEs on a multi-layered approach.

### 6.8.1 Multi-layered Analysis: Intellectual Property in SMEs

Figure 43 clearly illustrates how intellectual property rights are reflected by Biopharmaceutical SMEs. Evidently, intellectual property is recognised as being an important feature of all SMEs in the study which can be clearly accessed based on a **multi-layered** analysis level. As it plays a significant role, all SMEs with an exception of one, which is at an early development phase, IP rights are exercised to secure the novelties and innovative technologies of the firms.

**Figure 43: Significance of Intellectual Property for SMEs**

CEOs have stressed the significance of intellectual property during the interviews as being:

- a. Crucial
- b. Essential
- c. Fundamental
- d. Very significant
- e. Primitive

Evidently from figure 49, intellectual property plays a vital role in securing a firm's assets, and in the case of the Biopharmaceutical sector, its importance is highly recognised as half of the participating CEOs considered intellectual property to be a crucial element of the process of their firms. For a small number of SMEs that are financially backed by venture capitalists and angel funds (entities) who have a say in the operations of the firm, it makes it essential and necessary to secure their ideas and technologies with patents. This occurs as the dependent relations between a firm and a VC is based on the progress of the firm in developing exist strategies in case a VC wishes to exit.

A significant number of CEOs considered the position of utilising IP as *“a fundamental part of the business, which is a way of fortifying the knowhow of a new novelty”* (SME-08). Several CEOs characterise their approach to IP to be a significant part of what they do, as *“not only is it securing the knowhow and*

*technological input, but it is also a way of advertising and obtaining investments from various funds” (SME-05). A minor proportion of CEOs considered their IP to be primal, as “the sub-sector is not populated by new technologies, because exiting intellectual property is available to the public domain” (SME-20), as the particular technologies became generics.*

As section 6.8.1 indicated that intellectual property is considered a significant aspect for any firm, the following section 6.8.2 explicitly represents how the IP portfolio of the participating SMEs is managed, in order to have a clear representation of whether or not IP is considered significant by Biopharmaceutical SMEs.

### **6.8.2 IP Management**

To examine the significance of intellectual property, the study evaluates the management of the IP portfolio of SMEs, which can show if it is considered with high importance. Through a specific question, the study assesses how the intellectual property is managed, and evaluates how the novelties and technologies of SMEs are controlled and why the firms choose the specific way. In doing so, the use of retroductive reasoning will identify the entities or individuals that are responsible for managing and securing the intellectual property portfolio of SMEs, and the relation of their IP to open innovation.

### **6.8.3 Multi-layered Analysis: Intellectual Property Management in SMEs**

Clearly, there is a tendency in companies to choose patent attorney specialists to manage their intellectual property portfolio. The reasons why such strategies are adopted can be established by the facts CEOs indicated as:

- A. *“A patent specialist has the skills and knowledge to protect the portfolio of patents as they are experts in the field” (SME-09).*

The relations with patent specialists are built through the interactions with the CEO who has either association or experience in working with patent attorneys and specialist.

- B. Various patent firms approach SMEs with the intention to become their attorneys, by making a tailor made arrangement for a fixed period of time.

On this, CEOs indicated that they do not exchange quality over cost therefore it is preferable to work with patent specialists rather than carry out the patent process internally.

- C. Patent specialists create awareness by filing patents in different areas and families in wide spread locations, be it is UK, Europe, USA and Asia.

When a CEO in an SME wishes to expand the firm's activities abroad, a patent specialist in the location of expansion is *"always needed to draft the IP rights without creating any surprises"* (SME-05). In view of this, the CEOs are willing to pay the extra cost rather than jeopardise a potential expansion to a different market.

The following section 6.8.4 evaluates the possibility of IP management change, particularly why and how CEOs might change or alter their direction in the future. Moreover, section 6.8.5 describes the management of IP portfolio on a multi-layered approach.

#### **6.8.4 Change in IP Management**

To examine the future of the portfolio management, the study assesses whether or not the firms are willing to change their current strategy.

Noticeably, CEOs have indicated a reluctance in changing the portfolio management (83%) of their company as it consists of their property, which is either a novelty compaount or know how. This lies within the judgement of the senior management, which decides whether the current approach is the best option or not, as through their causal power, as CEOs , CSO and business directors are responsible for the implementation of the firm's strategy.

### **6.8.5 Multi-layered Analysis: Intellectual Property Portfolio Management in SMEs**

The majority of CEOs are pleased with the progress of the portfolio protection, therefore there is no need to change their strategy. In addition to that, professionalism is characterised as a form of reliability which CEOs prefer over cost, therefore it is preferable to be kept on that level. In an area where detail plays an important role, it is vital for SMEs and also large Biopharmaceutical firms to secure their position hence a professional assist is an important factor.

On the other hand, some SMEs are considering employing a patent specialist on the premises, where they can have full control of what goes in and out of their portfolio. As the firms progress, there is a possibility of becoming successful and large in size, therefore the employment of an internal team that will be responsible is always an option for SMEs. Similarly, a small number of firms keep the IP protection in-house as they have the necessary capabilities, such as the expertise of a CEO or a chairman who is a patent attorney specialist. In addition, costs of maintaining IP are escalating as the firms' technologies are increasing, which means some CEOs prefer to keep their IP management within the firm rather than to an external associate. As it has been stressed by a CEO:

*“The current approach is unlikely to change, so we will continue to use external patent attorneys as we need the necessary expertise” (SME-06)*

This shows how protective CEOs are regarding their intellectual property and their reluctance in adopting strategies that might change the structure of their IP portfolio. Although all SMEs with an exception of one have intellectual property, not surprisingly only a small number (27%) is willing to openly engage in IP outsourcing or insourcing. It has been identified that due to their size, the specific firms are more protective when it comes to their IP, as in many cases it's the only proof of concept, particularly when CEOs are on the search for external funding, particularly from VCs and other large funding organisations or associations.

What has been identified throughout the interviews is that internal structures with their causal powers restrict the firm from opening their IP portfolio. Due to the fact that it might be a risky movement as there is always the case of theft or misinterpretation during a joint agreement, CEOs and senior directors do not easily alter their portfolio management processes.

It must be stressed that in an industry such as Biopharmaceutical, links between brokers (innovation intermediaries) and Biopharmaceutical firms exist when capabilities are inadequate or short (Gassmann et al, 2008). A way by which firms can access and leverage their external knowledge is to work with an innovation intermediary which is an “organisation or body that acts as an agent or broker in a particular aspect of the innovation process between two or more parties” (Howells, 2006, p. 720) which results in helping “innovators use external ideas more rapidly” (Chesbrough, 2006, p. 139). The study assesses whether brokers create tensions or facilitate innovation in SMEs in a multi-layered method in section 6.9.

## **6.9 Engagement of Agents and Brokers with SMEs**

SMEs have a positive attitude towards using and employing the assistance of brokers and agents in their innovation processes.

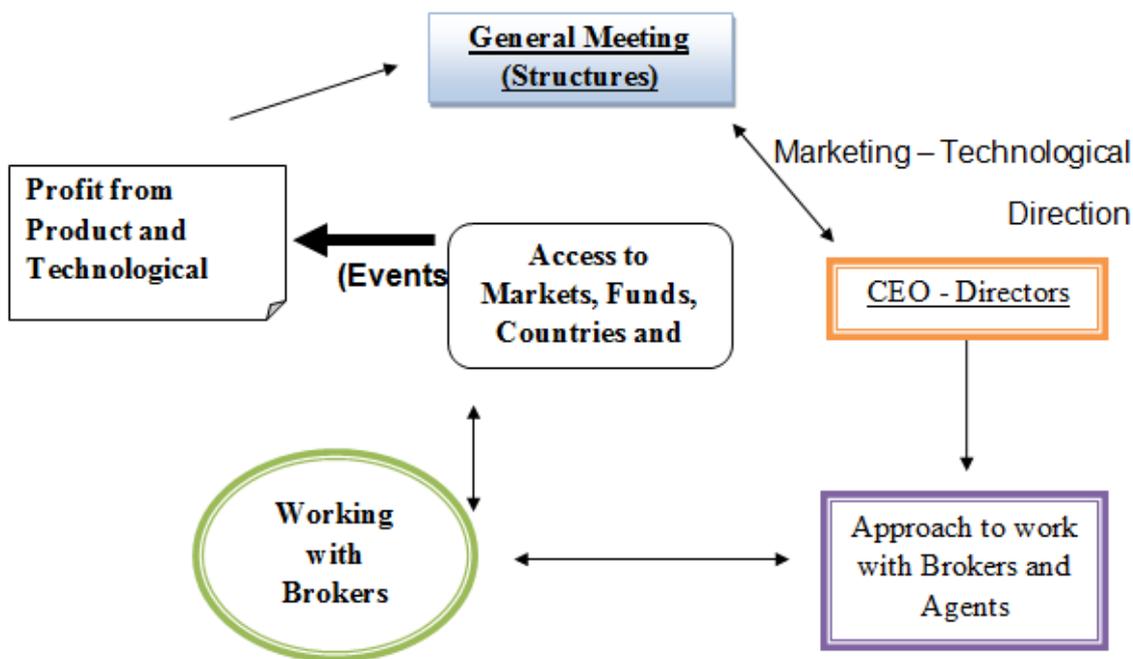
It has been identified that intermediaries that can work as brokers or middlemen can create markets for intellectual property, which can evolve in an open innovation ecosystem (Chesbrough, 2003a). What innovation intermediaries do is to “create value for clients by identifying, accessing, and transferring solutions to problems in various stages of the innovation process to their clients” (Hargadon and Sutton, 1997; Verona et al, 2006; Nambisan and Sawhney, 2007; Sawhney et al, 2003).

Business relationships within a firm are seen as social structures. Critical realism sees social structures as ontologically real entities, which like other social structures, might change over time, as they have emergent powers to cause events under certain conditions. (Bhaskar, 1978) Therefore, with the use of critical realism the study can examine the empirical level, such as the situations and events of which the CEOs and directors have been experiencing

during the process in which the business activities develop the actual processes which deliver the decision of working or not with knowledge brokers.

Figure 44 clearly classifies the processes in which the choice to work together with brokers or agents is adopted from a firm and how that mechanism works (Sayer, 1992, p. 11).

**Figure 44: Innovation Process Structure Engagement with Brokers**



Adopted from: Sayer, 1992, p. 93

### 6.9.1 Multi-layered Analysis: Agents and Brokers in SMEs

By employing a **multi-layered** framework, the study can trace the events and the necessary and dependent relations that trigger the processes and in what way. At the micro level, the study identifies the one to one contact with individual brokers and how that affects the firm. The study traces potential broker influence in terms of bringing firms together in resolving potential technological setbacks at the meso level, and lastly at the macro level, the study identifies the broker or agent influence at a national and international level, such as the MHRA and FDA.

The study shows that the majority of interviewed CEOs (57%) do not use the services of agents or brokers with only 43% doing so. Firms that do not use agents or brokers in most cases are doing so as the **necessary and dependent relation** within the firm, such as a Chief Scientific Officer handles the broker part of the technology or the further development of the compound. It has been identified by several CEOs that when a compound reaches the point where internal capabilities cannot take it to the next phase, then a knowledgeable scientist with connections steps in. In these cases, the brokers create the necessary **events** in which their personal relations with other individuals in research organisations and institutions assist in solving the current technological issue. For example, a CEO considered himself as:

*“Rightfully or wrongly an expert in the field” (SME-10)*

Furthermore, several CEOs stressed that their **necessary and dependent relations** such as an internal department of marketing, is responsible for the pricing, ROI and distribution of the product. So, when issues arose regarding rules and regulations, the firms that do it internally rely on the expertise of their staff (Chairman, Chief Scientific Officer) to create the necessary **events** in order to have the best possible outcome without jeopardising the firm’s core technologies. Therefore for some firms, the use of a broker is more like a burden than a help.

There is also a significant proportion of CEOs who argued that the use of either internal or external help regarding representation or deal making, is not on the current list of priorities due to the fact that their ideas, compounds or technologies are still in the early research or development phase.

On the other hand, a significant proportion of the respondent firms do use the services of brokers and agents who, through their **necessary and dependent relations**, produce the firm’s press releases and relations and create **events** such as presentations. Several CEOs emphasised the importance of having external experts working for their firm, as:

*“The strength of the business is being built around relationships and partnerships, and the more you build, the more the return you will have, especially in an open approach” (SME-22).*

Brokers are always present and in many ways, through **necessary and dependent relations**, assist the firm by creating a network in which the firm generates business, with these particular networks including corporate partners and other liaison advisors. This could not occur otherwise, as the firm is focused on a particular area and dealing with this part means that the time that could be spent on research and development must now be transferred towards seeking contacts, companies and other various industry key players. Additionally, brokers and agents through their **necessary and dependent relations** can get access to “grant funds, as they are people who are specialised in areas where non-diluted funding exists”. Now, when the decision is made by a CEO, the broker will create **events** such as tensions between the company and other companies and institutions within the industry in case the firm reaches its maturity and the senior management decide to sell the assets of the firm.

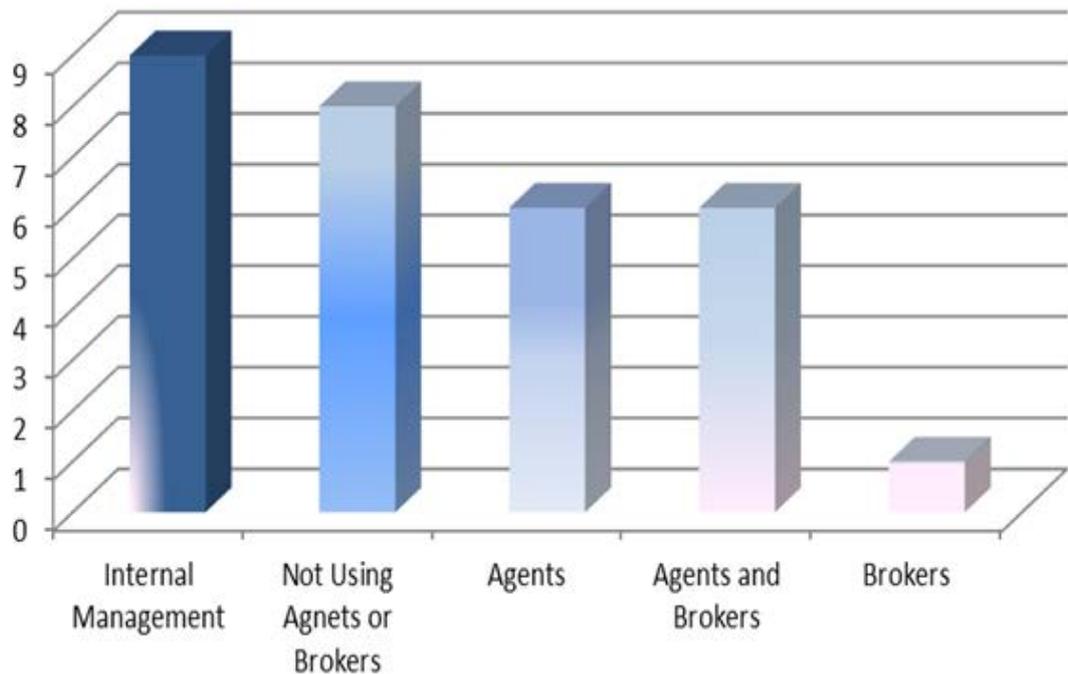
**Events** such as product placement at a national and international level, legislation boundaries in other countries such as the USA, Japan, India, China, the EU and Africa are elements which brokers utilise during their presence. Firms find it better to hire an agent which can deliver deals within other countries as the agent has the experience and the **necessary and dependent relations** to negotiate a deal as they:

*“Exist in order to help the firms expand in these countries in a very active way”.*

The “*gatekeeper influence*” as it has been stressed, is a factor which CEOs have in mind when they decide to work with brokers, as through their **necessary and dependent relations** they can move the legislation hurdles of a compound easier as they are experts in their field. The CEOs understand that to enter a market such as the USA or Japan, you need the necessary expertise that will assist your firm in selling a product or a technology. In doing so, companies trend on using representatives or distributors who through their knowledge can build **necessary and dependent relations** that can promote the firm’s interests abroad.

Figure 45 illustrates how many firms use agents and brokers, have their own internal marketing management or nothing at all.

Figure 45: Use of Brokers and Agents by SMEs



Clearly, some CEOs are not using agents or brokers as their size and current progress does not require one. Moreover, a large portion of CEOs prefer to manage everything internally. On the other hand, several CEOs understand that to become successful you have to use the best help possible, even if it means that it has to come from outside. This gives SMEs a strong position as without their help, the firm would not be in the position it is today.

Sections 6.9.2 describe the impact of knowledge brokers with the use of a multi-layered approach.

### 6.9.2 Multi-layered Analysis of the Impact of Brokers in SMEs

To value whether brokers and agents have a positive or a negative impact on firms', the study identifies in the **multi-layered framework** the **underlying mechanisms** which bring agents and brokers on the path of the firm.

The CEOs have identified that the majority of SMEs have a positive impact from the use of agents and brokers, or at least to a degree. It has been identified that the difficulty of a CEO is surrounded in finding the suitable representatives for their press releases and complex issues, which urges the use of an external

professional. Issues cannot be traced as companies don't have the absolute control of what the agents might or might not advertise, as different firms give different commissions. This creates tensions between the CEO and the broker, as CEOs identified that insecurity is a reason why firms allow a representative to be responsible for their invention in other countries, and how it can be guaranteed that the product will be approved in the particular country or continent. An important aspect for every CEO is the fact that through their **necessary** and **contingent relations**, they can establish links and connections between individuals, firms and organisations.

On the other hand, brokers have a very good record according to the respondents they are in contact with:

A. Expert individuals and various academic groups.

In doing so, the brokers create tensions as the basis of their methods is to help themselves by assisting firms into further developing their technologies, compounds and products, and also to remind firms when to put things forward.

B. Brokers and agents cause an increase in a firm's selling efforts.

This is done by ensuring that everything is in order in terms of product development, managing the field projects and building academic credibility when they publish their consolidated results.

C. Can cause tension a national and international level.

Through their generative methods brokers can create situations regarding funding and product placement, in markets such as China, Russia and Africa.

In general, the attitude of CEOs regarding brokers and agents is progressive, as they have causal mechanisms that in many ways can lead to the expansion of a firm's technological activities. Although there are a large proportion of firms' not using agents or brokers, they do so knowing that at some point they have to, as they cannot become a distribution company or a marketing organisation. As for the CEOs that utilise internal management, they have

recognised the significance agents and brokers have, hence they decided to have an internal team dedicated for that reason.

## 6.10 Conclusion of SMEs

With the use of retroductive reasoning, the study identified that the senior management (*entities*) of the particular SMEs are, mainly reluctant and biased (*mechanism*) towards adopting (*causal powers*) a novel technique; this might result in sharing their IP, which in turn is considered as the main outcome of the research and development activities. The agenda or personal perspective of individuals such as CEOs and senior directors is responsible for every aspect of the strategy in SMEs, either under closed or open innovation practices.

The study identified a significant proportion of SMEs (27%) are utilising a fully open approach towards innovation. It has been acknowledged by the CEOs and senior directors that SMEs use a variation of techniques and models during the progress of their innovation processes, varying from closed to open innovation with different approaches between the spaces. This was hugely significant that CEOs were keen to collaborate with external partners, firms and associates for technological gains. Nonetheless, it does not necessarily denote that the particular collaborative agreements and networks are done under the open umbrella, but under various circumstances and situations.

Evidently, the management of SMEs (*entities*) is protective (*causal powers*) in terms of their IP portfolio share, as only a limited number of firms have been identified as being willing to exchange information concerning their IP (*mechanisms*). Even if it is for the expansion or better facilitation of their internal technologies and capabilities, SMEs have a protective stronghold against sharing any potential technological gains. Although a number of CEOs identified open innovation as their main strategic approach, in terms of IP sharing, they show reluctance due to the fact that their portfolio consists of a limited number of patents.

Even though open innovation has been praised by the literature as a new and novel way in which innovative technologies can occur, SMEs are not in agreement. CEOs are more protective towards their technologies, since it has

been indicated that most of SMEs are built around a small number of technologies. On this, an open strategy can be implemented but at the same time the approach of CEOs or the culture in which they were doing business has to change; this can lead to internal issues and barriers in the regulations of the internal development process and the control of the collaborative project. Furthermore, from the analysis, it has been recognised by a significant number of CEOs that SMEs are exploiting the assistance of brokers and agents, as they are considered experts in their field. At the same time, the majority of CEOs have indicated that “*rightly or wrongly*” they consider themselves as experts, and any use of outside assistance is unwelcome.

The study recognised that the majority of CEOs and senior management of SMEs have a protective position towards their technologies, which is reflected by their unwillingness to share their findings and research and development outcomes. This by itself works as a driver of negative perspective as: “*A small company with big competitors can’t be totally open in terms of innovation, thus elements of open innovation can be used, but not as the main strategy, as there are protection issues*” (SME-05). This indicates the scepticism of CEOs in opening their boundaries towards open innovation strategies and practices.

Following chapter 7, the study clarifies the position of knowledge brokers through semi-structured interviews, who have a record of deal making and a strong background in terms of their involvement within the Biopharmaceutical industry.

## **7. Position and the Role of Knowledge Brokers in Open innovation**

The second part of the analysis, consists of the investigation of open innovation from the knowledge brokers' perspective. These brokers work as intermediates between two or more parties, and through their necessary and contingent relations can create tensions between the two parties. The study utilised semi-structured interviews with knowledge brokers and industry specialists, who have a proven record of deal making and a strong background in terms of their involvement within the industry. These interviews covered the following aspects.

- The perception of brokers towards open innovation
- Involvement of brokers in open innovation projects
- Research and development capabilities during open strategies
- Intellectual property in open innovation
- Involvement of Biopharmaceutical associations
- Barriers during open innovation processes

Semi-structured interviews were utilised with 8 knowledge brokers and industry specialist within the UK Biopharmaceutical industry. In the following sections (7.1 - 7.7), the study reviews the main evidence and findings from the research interviews on a multi-layered approach.

Arguably, the position and the role of innovation intermediaries is to assist in value creation of the various stages of the innovation process of their customers, through the identification, assessment, and transformation of problems to solutions (Hargadon and Sutton, 1997; Sawhney et al, 2003; Verona et al, 2006; Nambisan and Sawhney, 2007).

Specifically, innovation intermediaries are considered to be:

- A. Individuals,
- B. Organisations
- C. Groups within Organisations

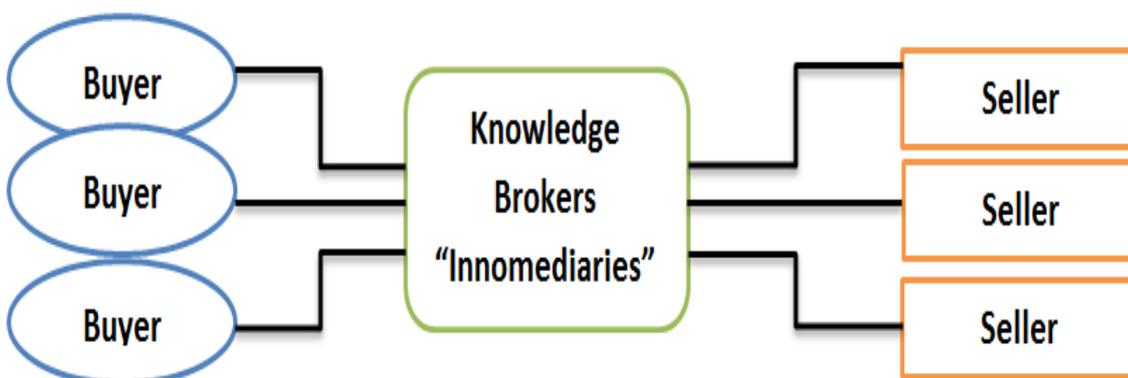
Their goal is to work as enablers or catalysts of innovation, either directly by enabling the innovativeness of one or more firms, or indirectly by enhancing national, regional, or sectorial innovative capacity (Dalziel and Parjanen, 2012; Dalziel 2010; Howells 2006). One of the ways by which firms can access and leverage external knowledge, is to work with:

“An innovation intermediary, which is usually an organisation or body that can act as an agent or broker, and in some aspect or sort of innovation process can build connections between two or more parties”, (Howells, 2006, p. 720).

In doing so, the brokers can help innovators utilise external ideas more quickly and efficiently (Fabrizio, 2006, p. 139). Innovation intermediaries can also help technology providers to find buyers or licensors for their technologies, and in return, allow technology buyers to use technologies of external origin in a rapid and beneficial fashion (Chesbrough, 2006; Gredel, Kramer and Bend, 2012).

At their fullest application, knowledge brokers are a part of a firm’s value creation either directly or indirectly, where the links between the brokers are knowledge transactions with the intention of gaining knowledge exchange (Mariani, 2000). Sawhney et al, (2003, p. 77) described the process in which an innovation takes place with the assistance of knowledge brokers as “Innomediation” as it is a mediation of innovation between two or more partners (see figure 46).

**Figure 46: The Innovation Marketplace Operator**



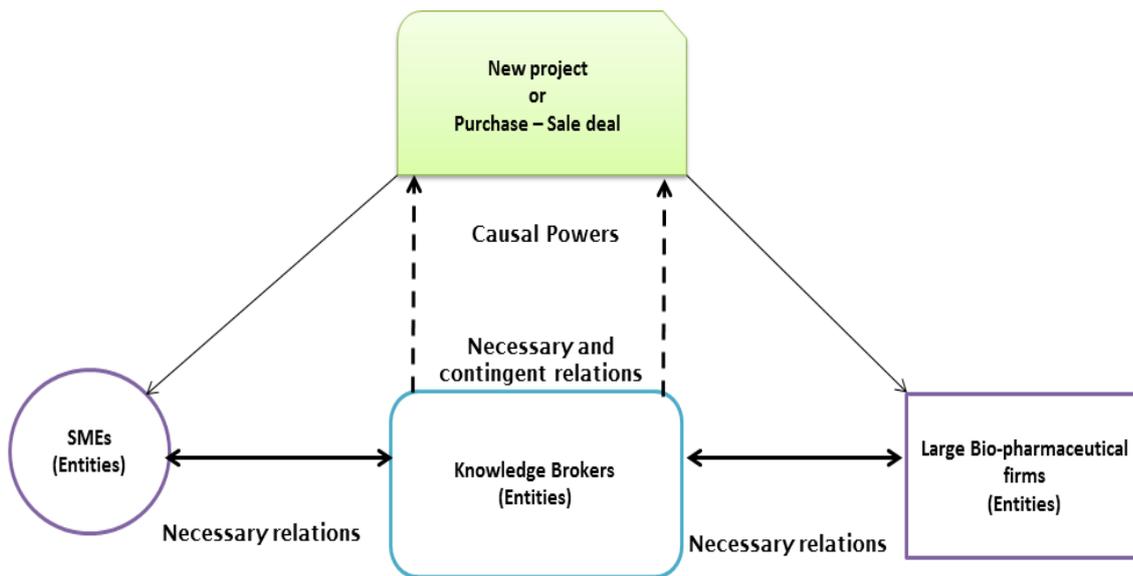
Source: Sawhney et al, 2003, p. 79

Recently, with the introduction of more complex models of innovation such as open innovation (Chesbrough, 2003), which consists of multiple or global partners (Bessant and Moslein, 2011), the need for intermediation has increased (Howells, 2006), as the relationships have become more complex and multi-faceted. It has been identified that outside sources of knowledge and information are often critical to the innovation process therefore the ability to exploit external knowledge is a critical component of innovative competences (Cohen and Levinthal, 1990). Nowadays with the expansion of open innovation within the global market, firms are increasingly considering the assistance and support of intermediaries for capital access, market expansion and technological gains.

Brokers are seen as an essential aspect for creating networks to firms with governmental and global projects and also funds through their extensive network of connections within the global Biopharmaceutical market. Moreover, as the economic downturn brought a limit on investment in the Biopharmaceutical sector, it actually encourages firms to partner with people that have a more resources than them, so being flexible is a way for firms to achieve a successful result.

Open innovation has been argued to support the use of innovation intermediaries (Chesbrough, 2006), therefore our study which focuses on the Biopharmaceutical industry, also consists of intermediates and agents, which are both imperative and necessary to evaluate a firm's approach and input. To evaluate the presence of knowledge brokers in the Biopharmaceutical sector, the study adopts a critical realist perception (Bhaskar, 1975) as the entities (brokers) have powers (connections and networks) to create events and deals (sale, purchase or exchange of privileged information). As figure 47 describes, by adopting critical realism, the study uses retrodution to explain how and why knowledge brokers assist and work within the Biopharmaceutical industry by identifying how the necessary and contingent relations take place (Sayer 1992).

**Figure 47: Engagement of Brokers and Agents**



Adopted from Sayer, 1992, p. 93

To understand where, in terms of research and development, Biopharmaceutical firms out-source or in-source techniques or ideas through effective collaborations with various individuals or institutions, the study formulate the necessary questions regarding the approach of firms towards such strategies.

## **7.1 Brokers' Perceptions of the Significance of Open innovation for the Biopharmaceutical industry**

Brokers generally provided evidence for open innovation operations across a multi-layered approach, as they can operate at all of these micro-meso-macro levels. Furthermore, interviews with brokers displayed the highest levels of knowledge regarding the open innovation approach.

Brokers perceive that open innovation is taking place currently in the industry, as it is one of the ways in which firms can acquire:

- a. Skills
- b. Resources
- c. Collaborations

At present, some examples have been identified, such as GSK and Lilly who are utilising open strategies, as they recognise that they have an internal innovation deficit and cannot do everything by themselves. It has been acknowledged by the brokers that large firms and organisations don't want to be "*blind-sided*" by a particular disruptive technology that arrives on the scene that they were not aware of. Now the reasons why it has been adopted from Biopharmaceuticals can be found within a combination of levels, as it gives them an advantage to go over their R&D budget. This means that they can accomplish more by opening their boundaries rather than develop them through their internal capabilities. On this, it has been identified that there are many different ways of utilising open innovation, and it is now becoming clear that open innovation is not a panacea or a solution to everything, but rather one tool from the toolbox. A knowledge broker stressed that in an open innovation approach to do nothing is not an option as:

*"If you do not change you will die" (KB-02).*

At the same time the industry itself has recognised that it no longer has the monopoly of wisdom, thus becoming more open. Skilful scientists are always an essential source of innovative technologies and approaches, as the **connections** and **dependent relations** between brokers and scientists create the necessary links between firms and skilful individuals. This happens as there are benefits to be learned from other individuals, from whom many leading products can originate particularly through collaborative activities. In a similar way, brokers identified that they can bring firms together by matching problems with suitable or possible solutions. This has been identified that occurs either between large firms and SMEs or between SMEs to SMEs via their depending relations that trigger **mechanisms** and construct a deal between two or more parties.

To an extent, large multinational companies have participated with open innovation strategies, and P&G is identified to be a good example, but it is yet to be seen if it has generated results in the Biopharmaceutical industry. Nowadays, it might be observed that the Biopharmaceutical industry is adopting the example of the aerospace industry, which addressed some of its big manufacturing challenges in an open collaboration. In doing so, aerospace

firms successfully delivered several technological novelties, and at the same time resolved issues that would take years of internal research and development. The approach is not specific to medicines, but it is specific to technology for research, development and manufacturing, thus it can be applicable in solving the challenges during the progression of pharmaceuticals firms.

Now, on the other hand, although several people understand the use of open innovation, they are suspicious about it and do not understand how openness can work properly. What has come out of the study is that the real problem lies within the industry, which to date has some difficulty in understanding what the purpose of open innovation is. Knowledge brokers blamed that on the fact that several key individuals within the industry do not have:

*“The open mind-set or culture to engage in an open business model” (KB-05)*

This also occurs as the traditional blockbuster business model is embedded to their culture. The pharmaceutical industry has been characterised as a prisoner of its past successes (Gilbert et al, 2003, p. 73) which is now becoming extremely expensive (Chesbrough, 2007, p. 15), and at present it is difficult to change their approach from internal to external innovation. What has been emphasised is that if the open mind-set is not there, then the possibility of discovering skilful individuals and new technological inputs is minimised. This occurs as several key individuals within the sector are institutionalised in the traditional ways and are not thinking outside of the box. To this extend, it is embedded to the core competences of most firms (Prahalad and Hamel, 1990) that goods and services which are considered to be core should and must be produced internally (Arnold, 2000, p. 25). A significant drawback is the lack of confidence in the UK around open innovation, as it has been indicated that people are sceptical, a common element of the attitude in the UK. With the use of Nvivo Word Tree analysis in figure 48, the study elucidated further the perception of brokers towards open innovation. The Nvivo Word Tree identifies several aspects and reasons why firms in the Biopharmaceutical industry engage in open innovation agreements, based on the brokers' interviews.



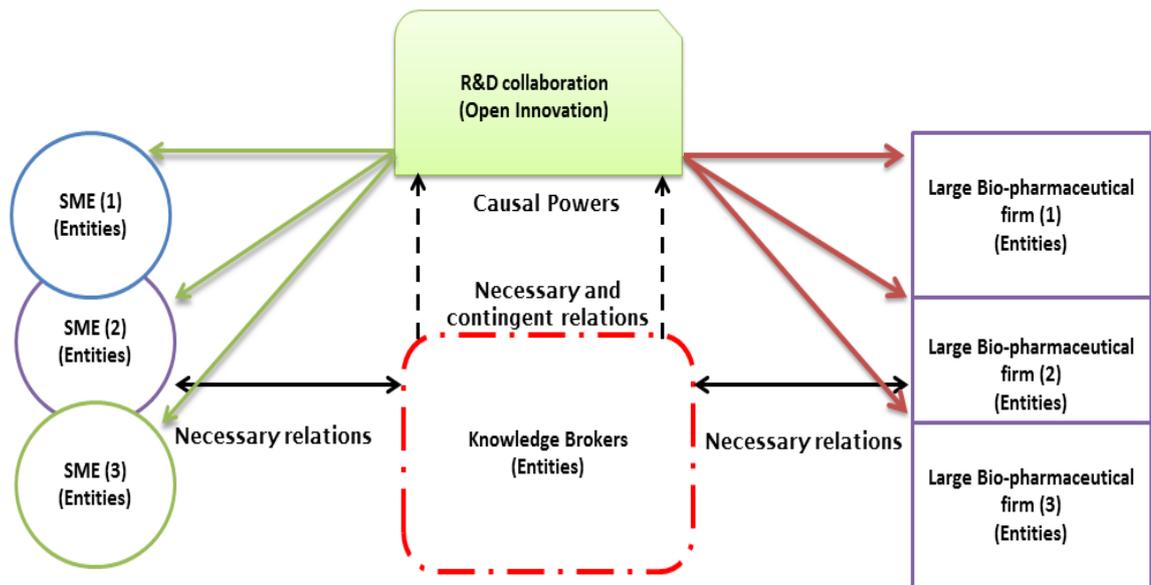
Figure 48 illustrates that the practice of open innovation is at the moment dealt at an early stage, where companies and individuals are talking about it a lot, and it seems it has become a **hype or buzz word** which has not yet delivered significant attributions. Although that might be true, it has been implemented by several companies and institutions but not in their core business models. To some extent, open innovation has been acknowledged as a new word for something that people have done in this area for quite a long time, and repeatedly stressed by brokers to be the “pre-competitive collaboration space” (KB-01/08). In addition to that, open innovation is considered by brokers as a nice term for something that might be idealistic and probably less easy to do in Biopharmaceutical, and particularly for small and medium size companies. It has been stressed that this can be the case, simply because in order to be commercial, the significant part of the intellectual property has to be patented to get capital support for the company, which is a vital point during the early years of research and development. Furthermore, it is evident that brokers understand how opening the internal boundaries can assist a firm in expanding its activities and profit margins, but they are *“not convinced that firms understand it as they should”* (KB-08).

To capture the significance of open innovation, the study identifies the importance of and the attitude towards collaborations under open innovation arrangements. As figure 49 illustrates, through their necessary and contingent relations, knowledge brokers assist firms by creating open and collaborative projects.

### 7.1.1 Attitudes during Open R&D Practices

As has been recognised, at the moment it is very common for Biopharmaceutical firms to engage in open innovation collaborations and technological expansion, but people who are responsible for taking action don't understand the concept as it should be. Open innovation is given high importance, and the brokers identified examples showing its success, both in SMEs and large firms such as the InnoCentive programme of Lilly.

**Figure 49: Research and Development collaborations in Critical Realism**



There is also some element of chance, as when collaborative agreements take place several potential angel fund investments might compete with each other and the low hanging fruit can be identified more easily. Based on that, it has been stressed that stacking up the odds by bringing in more people who can judge what is successful and narrowing it down, becomes more of a chance of success as the chances available through collaboration can increase significantly for a number of reasons:

- a. Having the right people (entities) driving it (causal powers), the open innovation approach can deliver significant changes (mechanisms) to the research and development processes of a firm.
- b. CEOs in small companies have to be the drivers of openness as they are the ones who can set up the terms and arrangements that will then developed into a working environment with larger partners.
- c. An important factor in any collaborative situation is the necessary skills to get to the market, which is done by having a basic agreement with all the individuals and organisations that assist in areas where internal capabilities are weak.

- d. It is important to work in open arrangements, as companies can easily identify the competition. Interviewees recognised and stressed that going into open innovation not by seeking the personal interest, but with an open hand, and recognising that is going to be transparent where everything will be put on the table, is always a win-win scenario.
- e. Arguably no one has the monopoly of wisdom, therefore is always better to discuss internal ideas with external associates.

Knowledge brokers stressed that people in decisive roles tend to be risk averse and particularly in large pharmaceuticals where there is generalisability towards increasing the shareholder value. Therefore, although they have their own agenda, at some point they have to say that it is becoming everyone else's agenda when engaging in open projects. Having a competitive process to partnering with individuals such as academics and biotechnology scientists it is always acknowledged as an open business progresses. By operating alone, the area of internal expertise is narrow and it has been characterised as "*stubbornness*", as firms are seeing it as a form of competition rather than collaborative engagement. For example, one broker described a case of collaboration where open strategy was applied.

*"Two firms, identified each other as they had capabilities of solving each other's objective, thus they prepare a joint collaborative agreement with the intention of mutual benefit. The arrangement clearly underlined that in return for firm A to engage in the collaboration and provide its skills, it would have the rights for all centralised laboratory testing of firm B, which secured the results and the market for testing the specific method in the region or area"*  
(KB-08).

So, on the one hand there is the company who profited from a collaborative agreement without having to spend millions in developing a test, and on the other hand a firm who become a leader in the field by securing the testing of the technology for decades. During this particular project, the skills and attitudes of the related people in the key positions was clear from the start, thus making the arrangement a successful story.

Now for a firm to engage in open business models, it has to have an open attitude on all three multi-layered levels. It has been expressed that scientist coming from academia are actually open towards the academic environment, and people that come from another pharmaceutical company may be quite open towards the industry and academics.

*“An example was seen in some firms where they collaborated because they had two people in a team who were good at a specific area, and they wanted to build a service business where their testing could be done, and so with some grant money and collaborative projects they could achieve that. By engaging in the collaborative space, they employed three more people for a couple of years and by the end of it a department of five people with track industrial records could be achieved as a separate entity tied to the firm” (KB-04).*

Interviewees stressed that in the pharmaceutical sector it is still too early to say that open innovation is successful and even though examples of success exist, it is still an on-going process, so no profits can directly be identified from such activities. Some agreements over the last few years or so with open innovation arrangements were identified, but the sector uptake is very slow, as it is difficult to work out **“what everyone who is involved actually needs” (KB-01)**. Furthermore, the benefits of open innovation in the pharmaceutical industry are hard to be measured, as the product cycle of an NME from the research until the actual commercialisation is a very long process. It has been described that going into open innovation by first asking *“what is in it for me? rather than going in with an open hand, will not be beneficiary as the partners need to recognised that it is going to be transparent” (KB-08)*. It has also been identified that no one has the monopoly of wisdom and therefore is always better to discuss internal ideas with various internal and external scientist as well as industry experts.

Several steps were identified that are needed to become more open, but first of all there has to be a willingness of the involved people to share a problem with others, either with academics or with pharmaceutical companies. Furthermore, firms must have a will to share that information with the industry and the rest of the world, as it could be something valuable. By opening it up it will allow others to provide solutions to specific problems, things that have not always

been in place. Several examples were identified where early open innovation strategies were applied such as:

- *“A pre-existing form of open innovation which involves the local stakeholders in the micro, meso, macro is the development of anti-retrovirus attacking HIV, where several people come forward in the 80s, including large pharmaceuticals, regulatory bodies (FDA), universities and academics, and through that collaboration what we have now is that HIV is considered as a chronic disease rather than the killer disease” (KB-04).*

This particular example shows that early open innovation practices consist of the multi-layered approach as it involves various academic groups and scientists, Biopharmaceutical firms’ particularly large and government bodies such as the FDA.

- *“A pre-competitive open innovation arena where people share ideas for a common goal is to identify the end point of mutual benefit. In this space, the IMI which is the innovative medicine initiative of the European Medical Information Framework (a part of the frameworks), brings the pharmaceutical industry and the European commission together in a €1 billion deal for pharmaceutical support, by which the main goal is to address the challenges in drug discovery by bringing academics, biotech and pharmaceuticals companies” (KB-05).*

The IMI initiative was a collaborative effort which was triggered through the European Union which aimed, in a multi-layered space, to seize the opportunity to create as many solutions as possible to drug discovery issues and barriers.

- *“A prospect where open innovation can be applied is in Alzheimer’s disease, as it is not clear how to address these issues and by bringing groups together it would create a better understanding of what must be done to overcome the potential barriers”(KB-04).*

This particular case was indicated as a potential example for open innovation use, as it contains elements which, if shared openly between two or more

partners, can lead to the creation of a successful candidate for a disease that has not been treated successfully so far.

One of the possible uses of open innovation is for the discovery of a molecule or the way to deliver the drug to a patient and get the clinical outcome. As there are thousands of potential issues, and thousands of questions, brokers stressed that there are potential opportunities for open innovation application, although some of them might not be able to monetise.

*“Drug discovery could be an example of something as simple as a clinical supply chain, or by simply developing a way to ensure that the biologics that are used can actually be applied in a variety of climates and has a longer life use” (KB-01).*

The broker groups acknowledged that on an **individual** level and between **firms**, creativity and multitasking abilities (causal mechanisms and powers) are crucial, since meetings will take place to clarify the end point of each side. It can be recognised through the progress how it can be helpful to each other by either solving problems or covering needs that would be worthwhile rather than the internal research and development. For the **industry** to get a product to the market it is not all about R&D, there is marketing, product manufacturing, distribution and areas for open innovation engagement. Furthermore, the patent and the intellectual property, which includes the discovery, the mechanisms, and the manufacturing process in detail, can be exercised to deliver a better package, a better fermentation process, or smarter ways of identifying the right group of individuals.

### 7.1.2 Benefits of engagement with open innovation processes

As the uptake of open innovation is being increasing, the study has identified involvement or participation and benefits for the involved stakeholders at a multi-layered level.

Some examples of success have been identified, where companies of two or three partners have worked together and it was clear that not only the companies benefited but also the stakeholders and shareholders. Figure 50 shows the process in which stakeholder gains through open collaborations

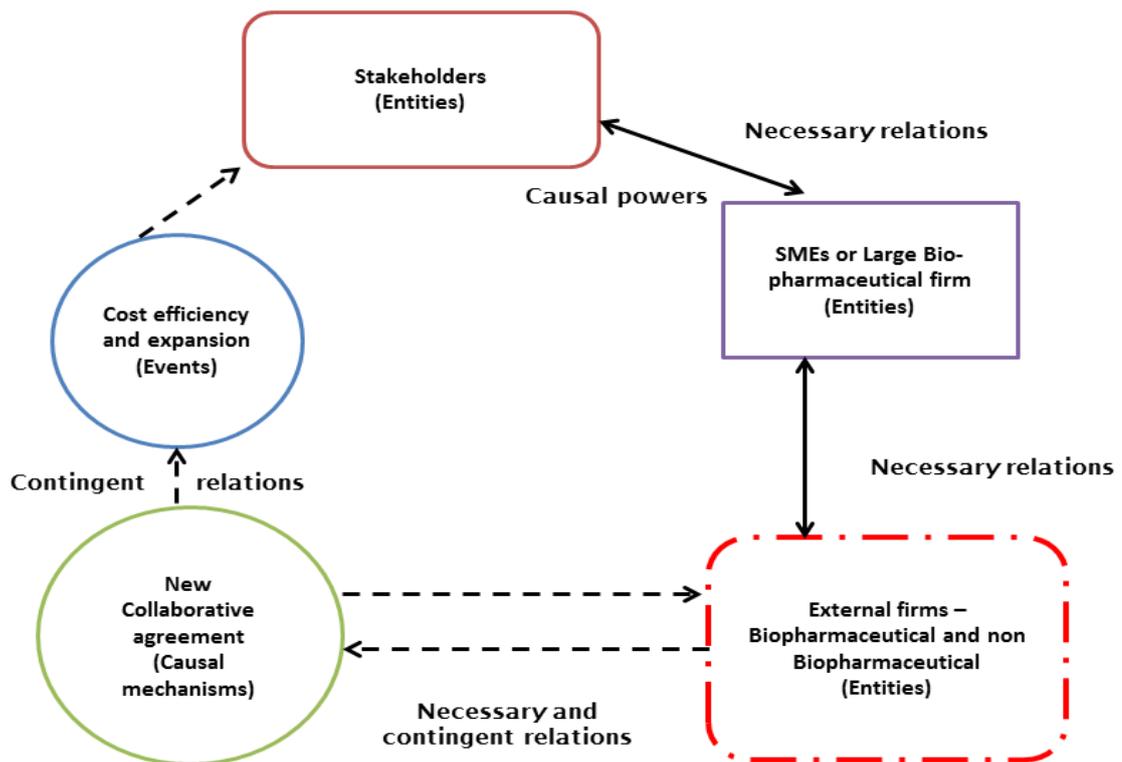
based on a critical realist viewpoint (Sayer, 1992). Evidence for these gains was expressed at several levels:

*“A particular success case is a biotech firm named “Morphosys” which developed collaboration with one of the larger companies, and the core of the collaboration was a very valuable technology for screening compounds. By identifying that internal capabilities are not adequate enough to make the necessary suitable compounds, an engagement in a collaborative agreement was needed. So there has been some very well documented collaboration between the two, where one identifies the biology and the other does the chemistry and they share the benefits” (KB-02).*

*“On a macro level, an example exists that consists of the direct involvement with the NHS which is quite unusual, but in that instance all parties managed to overcome some of the bureaucracy. The Health Department clarified that the entities that are collaborating are done under a government policy and have to be aligned with that, which is at the moment achieved. So that's an example on the micro, meso and macro where everyone is involved, including individuals, the representatives of firms and the government via the NHS” (KB-03)*

*“Noticeably, there is a particular collaborative arrangement in Africa, where some pharmaceutical companies and the Gates foundation are getting together with Coca-Cola, as Coca-Cola has the best distribution for cold material in the world (necessary conditions and causal powers), thus they are established, and any approach without their assistance is very difficult as there is no other infrastructure better than Coca-Cola in that area” (KB-04).*

**Figure 50: Stakeholder gains through open collaborations**



As it takes up to 15 years to develop a product, firms understand the difficulties and there have been particular examples where the industry and individuals were always working like this. Thus, there are companies with products in the pipeline that have been generated from collaborated early development in the precompetitive space. First and foremost there has to be a similar mind-set in a form of trust and then by matching each other's agenda can actually bring better and more rigorous results.

An example of such benefits was identified to be the: *“Latvian Institute of Organic Synthesis, a state funded institute, where they combine academics with different skills and areas and focus around the problem and debate how the new challenge will be tackled under a contract. Thus far it has developed 17 original drugs and invented more than 70 original preparation methods of known medicines (POLARIS, LIAA - Investment and Development Agency of Latvia), which is a high success rate given any industrial example” (KB-02).*

Similarly, as soon as a firm goes away from in-built defensiveness of core competences believing that *“the only value is achieved by putting walls around the firm” (KB-06)*, then individuals who take decisions can express their own

needs which are different from the approach they have at the beginning. Additionally, the Lisbon treaty priority <sup>17</sup>forces European Union countries to spend a percentage of their GDP on technological R&D development. This can be seen as an initiative that promotes the pharmaceutical sector which is among the biggest contributor of R&D expenditure particularly for the UK. On this, it has been stressed that the MRC together with a BBSRC funded programme of £35 million, have created the notion to collect several university laboratories with the main goal to generate an exploitable output from the specific laboratories. Now, a significant issue with public funds is that the money has to be spent prior to receiving the money. So the cash flow for a start-up company will be disastrous as by going for the public funds, a firm might go bankrupt because the money is spent three, four or five months before pay day.

As it has been stressed earlier (page 178), open innovation is seen to be more easily implemented within the small companies, where personal relationships and commitment are the core businesses, but due to their size and background, several small companies are averse in doing so. To work with the big company it is necessary to have "*a product champion*" (Chakrabarti, 1974) within the company to persuade the large company to invest or uptake in the specific technology. Arguably, there might be deals in the pipeline that have not been considered, thus it is vital for them to identify an end or selling point to exploit.

Furthermore, it has been argued that "*companies have to step up rather than keep their development internally*" (KB-06). With the intention to develop open connections they can create mutual trust and networks within the industry, as these networks will assist them in expanding their R&D capabilities. As it has been emphasised, the Medical Research Council and the BBSRC can create opportunities for researchers based on open projects, as they have direct access and connections to the industry. In addition to that, it has been acknowledged that the specific organisations arrange exhibitions which take

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<sup>17</sup>"The research and technological development (R&D) investment in the EU must be increased with the aim of approaching 3 % of GDP by 2010." (COMMUNICATION FROM THE COMMISSION COM(2002): 3.

place on a regular basis. During these meetings, academics are presenting their work to their peers and industrial partners, thus by doing so they develop a clear proof of concept and at the same time are gaining valuable experience through constructive feedback from the participants.

In open innovation then, the use of a knowledge broker appears to be essential/increasingly important as it creates links and networks through contingent and necessary relations between two parties or more. The study evaluated the position of brokers in open arrangements, and through retroductive reasoning, identified how that is possible.

## **7.2 Brokers' knowledge and involvement with open innovation**

Undoubtedly, brokers are evidently now trying to find new and easy ways such as the Internet or IT-based ways from newsletters and websites of matching people up. Particularly nowadays, where there is always the finance issue, as companies or individuals will not invest unless they are convinced about it, through the internet firms and individuals can prove their concept to funding organisations or venture capitals faster and better. In open innovation, knowledge brokers are seen as entities (organisations and or individuals) that facilitate the sharing of public (macro), industry (meso) and firm (micro) knowledge between knowledge sources and knowledge needs (Sousa, 2008; Gassman et al, 2008). It has been identified that a number of different sorts of individuals have come to be knowledge brokers and nowadays there is a greater presence of open access to people who are offering services. There is a necessity to have a direct contact between individuals and companies that are looking for each other so they can assess the trust, technological suitability and flexibility to work together.

Knowledge brokers come in different variations and some of them are actually serious scientist whereas others are more commercial, perhaps individuals that can understand the commercial aspect of the process better than the scientific (figure 49). An intermediate has been characterised as an individual who knows how to translate and understand a broad process of how deals are made. Thus, by utilising a broker, a company can diversify its activities, as there are many

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

things going on at the same time and are not done in the same way. A broker with knowledge and expertise (causal powers and mechanism) can assist a company to adjust the time spent on a project and to diversify from one product to another, whilst individuals such as CEOs within the company may not be familiar with this.

Although brokers can assist in the technological expansion, as they can use their skills to reveal what the best solution is, sometimes that might not be the best available result for them. In addition, the flow of information from the client is at the centre of the organisation to the intermediates, which are the knowledge brokers or someone within the organisation, and the issue particularly for small companies is that they cannot have very competent people working in the organisation to organise and arrange the intermediate action. The brokers identified that an approach for them should be working as advisors, to keep the initiative for the people within the company who have the idea and need the answer in the first place, or work externally alongside someone who is very well informed.

On the other hand, it has been reported that some brokers might create damage to the company, as they work on success fees themselves, so what they do in that situation is put themselves out to find funds for that company, but this suggests that the company's survival is totally in their hands, thus when time runs out it leads to a disaster. Now if the broker or intermediate is involved in an open arrangement, then it can be easily identified whether the broker arrangement works or not.

Brokers are becoming well motivated and have a very big network, as they have a reputation of being good networkers and good practitioners of wealth creation. Additionally, their presence is critical as in the case of a small company, what the company takes is an exit tomorrow which is what the investors want. On the other hand, what the inventor would like is to carry the research for the next 20 years, and what the big company wants, is to pay little money now and have absolutely everything. In such a case, a broker or an intermediate can mediate either position seems financial better.

Brokers identified that almost by default they bring together different interests, and speak knowledge from one side to the other and blandly manage to break

the deal. What has been acknowledged is that brokers seemed to be “*buzzing around*” and most of them are arguing that open innovation is “*what we were always doing, sharing information and matching technologies*” (KB-08).

Brokers often claim that they were doing open innovation by looking into firms and matching technologies around the sector, therefore their presence in open innovation is both critical and necessary.

Knowledge brokers are sometimes seen as somewhat devalued because a lot of people have considered themselves as knowledge brokers, but are actually individuals who were middle to senior managers of pharmaceutical companies. This is often the case with individuals specialised in some management functions without the overview of either corporate management or the sector. Intermediates are seeking for the necessary deals, but there are often big problems when working outside the hierarchy of a firm. At the same time, there are so many people doing the same job but are not offering the same level of competence and capabilities. At the end, there will be good brokers as well bad.

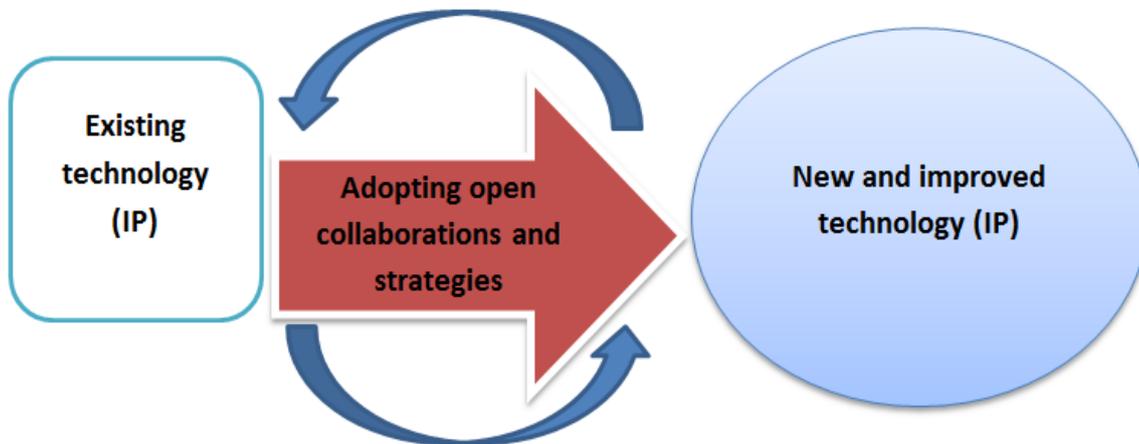
### **7.3 The role of intellectual property under open innovation**

On any given occasion, the intellectual property of a firm or an organisation is seen to play a significant role towards the development of the process and project strategy. IP is considered a vital point of every Biopharmaceutical company as it works as a protection of future product revenues in an industry which consists of extensive and expensive regulatory hurdles, high R&D costs, and inherent risks of failure in critical stages of the development (Trask, 2007, p. 302).

Effectively, IP is considered as an asset for a company to apply or use that best fits your plans, and it has significant value, which means that it will be used in whatever business model is developed with the open innovation partner. It has to be a part of what it will be used for, depending on whether the views are positive or negative as it can leverage the value from innovative efforts (Fredberg et al, 2008). A company in open innovation practices has to have risk

management mentality at the same time, so to know how generous or open it can be in order to develop a better technology, which is going to happen in the long-term as the IP protection is used for long periods of time. Figure 51 describes the advance of a firm in adopting open strategies and how IP is improved through the specific approaches.

**Figure 51: IP process in open innovation**



However it has been pointed out that small Biopharmaceutical firms with experienced scientists and managers understand what is going to happen to their firms if they would make the wrong decisions now. This might risk the opportunity for them of having a position to negotiate a deal in the future. An example which can be traced at all three levels is *“a company which made a breakthrough in diabetes at an early academic study phase, but did not wish to share the profits of the technology with a company that had a carrier molecule ready to place the new molecule on”* (KB-08). Eventually, it was disclosed that the regulatory authorities requested the firm to go through the necessary regulatory procedure stages, but now if the company had gone through the collaboration and used their molecule that was already approved; it would have effectively been holding a product.

It has been argued that if IP is exercised accurately then it is effective and critical for any firm or organisation. Working with partners from different countries and cultures is both demanding and critical. Individuals from different cultures and mind sets are always diverse, but by controlling who does what, can lead to success. It has been indicated that if it is kept

absolutely clear, the relevant IP will be enabled with full access to other partners and could lead to a win scenario.

Having efficient IP attorneys to collaborate with can lead to successful collaborations, as the legal issues are clarified ahead of the actual collaboration. It has been traced that by keeping absolutely clear that the IP is relevant to the areas that the collaborations are being used in, it will enable full access to the partners, which develop a mutual respect that is necessary in collaborative arrangements. By working with companies overseas, it is very likely to come along side academics that have developed a new technique or novel approach. An example of a bad collaboration at a multi-layered level was a new diagnostics technique that:

*“Could predict how a patient responded to a particular medication developed by an academic at Kings College in London but was shared with eight other big pharmaceutical companies” (KB-06).*

This was indicated as confusing not only for the academic, who invented the new solution, but also the university that could not push for exploitation and the companies that were involved, as it was very complicated to indicate who gets what. The fact is that it was a brilliant idea and it would have been a massive step forward, but due to the fact that it was so unclear who owned what it became a barrier for further exploitation.

Although IP can assist, it is sometimes less and less convinced that patent is always the best solution for universities, SMEs and equally to big companies. If an SME is really good then it should publish its results in respectful newsletter which will prevent others from copying it. But if they are after an un-commissioned partner and the publication is being made in natural science, then there is a notion that no one can make their individual patents in that projection, as when a patent is deposited to the USA, which is a large market, if the company is in a competitive position and the scientific position is strong, then it can move ahead with their project. In actuality, what it will be protected from is not just the basic patents of a molecule but the manufacturing process with the clinical derivative, and what happens to process patents is how the restriction access to it is made. Several reasons can be identified as to this and one is that in the past business development was done with smaller chemical

entities and not a real understanding of how it worked, or why they worked, and the basic safety regulations and clinical ethics forms were covered. But nowadays, regulatory authorities are preoccupied in taking action as the molecule has to be mechanically acceptable to put the necessary safety grounds, and face forward trials that are going for authorisation, which are becoming lengthy and costly.

The issue with IP in open innovation is what property is technically available for the development. Against the structural dynamics consortium, where drug discovery is a part and where working together is the notion, there is the notion of keeping the asset in a university for longer or in consortium, so when a company comes there will be a consortium that makes all the decisions to cut down the amount of patents in the early stages. The IP have the basis of the knowledge and novelty is protected for years and years in which investors put money in and can utilise in the market in due time, as it is the only way to capture revenues. The main reason is that the company or organisation holds something that has a value, and how that can protect the possible product which can be utilised in the future, is a constant battle in the open innovation deals and that's why open innovation application is very hard.

Embracing open innovation is considered a good strategic decision and the structure in a consortium is a good way of implementing such strategies. In the case of big pharmaceutical companies, it was stressed that they always want to invest in projects that involve the notion of *"there is a problem at an early stage of the drug discovery, thus there is the need to work together and avoid the same mistake. As the cost is huge it means having the powers to precede new things by being the busy one and getting too much attention"* (KB-07). In open innovation there are intractable data afflicting everybody and they are very common, therefore problems and answers to problems can be identified by sharing the value of the particular solution as it is difficult, not impossible.

A company's decisions regarding the IP that will be a part of the open process are not going to be the key drug IP into, but a process that goes around the main IP of the company. For example, the formulation and pre development data are often an effort that is shared during open progress. Now, when a contribution is revealed, the company tries to put it *"in-house by finding an*

*application of the particular project closely to their projects” (KB-01), and thus creating something related to their technology and process by redefining it for internal use. It has been identified that the pre-competitive which resembles the open innovation approach was an approach several pharmaceutical firms were adopting for many years.*

Nowadays, companies and individuals are considering adopting such an approach to understand that none of this happens overnight, so there has to be a very pragmatic approach and the stakeholders who are engaged must understand the journey and the time line. The basis of the IP in an open innovation strategy have to be very clear from the beginning since a strong framework can determine what is open and freely available and what is for commercial exploitation. A big problem is that a lot of individuals that are connected with open innovation projects must be clear about the level of innovation that is publicly available to everyone, which is not always the case. It is important to have clear IP regulations in the Biopharmaceutical industry because without this, the innovation cannot go forward.

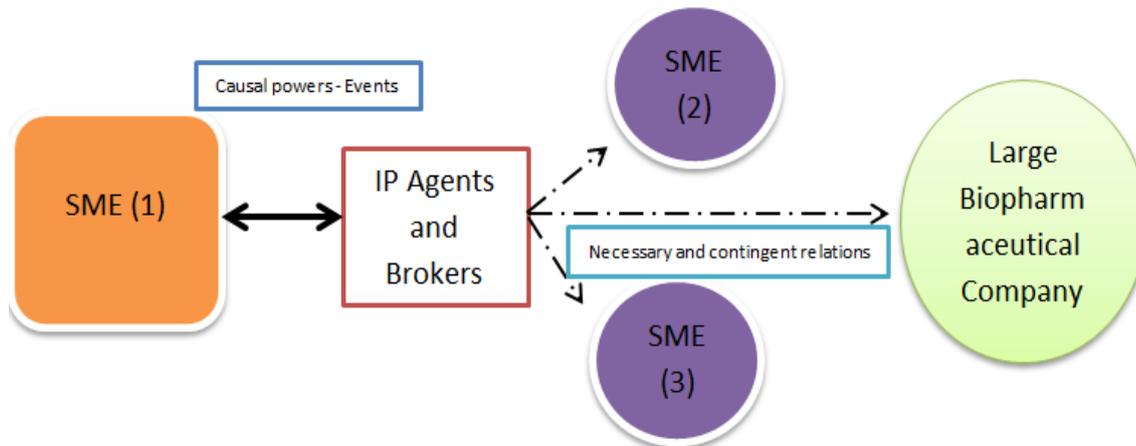
The following section (7.3.1) assesses whether or not agents or brokers interfere with or have a significant catalytic role in the development of the intellectual property during open projects and strategies. The study traces the existence of agents and brokers at a multi-layered level, as it involves several key individuals, Biopharmaceutical companies and regulatory and government bodies.

### **7.3.1 Involvement of Brokers and Agents with Intellectual Property under open projects**

Undoubtedly, in designing and protecting their IP, companies and institutions use the skills of external specialists such as patent attorneys, agents and brokers. To assess their agility and ability to create the necessary and dependent relations, the study evaluates whereas agents and brokers create tensions between small and big companies and if such an approach is currently applied, how successful it is.

Figure 52 illustrates the connections and relations agents and brokers provide within the open innovation context, in how effective they can be in terms of IP expansion.

**Figure 52: IP and the involvement of Agents and Brokers**



Brokers in all identified that in general, patent attorneys and patent agents consider themselves as advisers rather than as leaders. The opinion of a patent agent is definitely very important, particularly when they evaluate risks, but their main role is not to lead, is more of an advisory board. By understanding the fact that agents depend on the organisation as they are in the business to make money, the more time they can spend with a company the better it is for them.

Now a patent agent doesn't do the deal on behalf of the company, as the company has its own business development department or individuals (entities with causal powers). Thus, the patent agent protects and works on behalf of the company to protect the patent and not to act as a broker. Although they can advise how best to protect, they will base that advice on what they see in their perspective, and this is back to this pharmaceutical ready investment. So for them, the IP needs to be the right format so it will pass the diligence that the pharmaceutical would work for the particular case. But at the same time, to get Pharma ready the patent agent's sole role is to assist during the intellectual property process in a way that the value will be maximised. As their role is to be defensive, agents do not go out and try to broker a deal, as this is normally down to the internal business development, the CEO or an industrial broker.

They exist in the space but they are very protective and not at any chance will they share it with anyone.

Clearly, SMEs try to protect their every bit of knowledge with patents and if academic researchers are the founders who want to publish their outcomes, then it is necessary to have a patent beforehand. Nonetheless, it is very probable that later on in the research process more and new patents will be added on the original one or even replace it. Thus a firm should seek very carefully what to patent as it is very hard to sustain the increasing costs, so keeping the knowhow until the idea is much further developed is more efficient and less expensive for SMEs.

The initial investment in intellectual property at an early stage is characterised more or less as a gamble which most times is not paying off. This often demonstrates that when a company is at an early stage the management considers spending money on protecting IP, which probably will never be used. Clearly there is a need for managers from SMEs to work closely with patent agents to create the best possible deals. Similarly, large companies have a much greater census of secrecy and would be supporting such approaches. As in SMEs, likewise in large Biopharmaceuticals, the entities and objects responsible for the management of the intellectual property portfolio, designs the specification which the firm will follow, putting the agenda of the firm into the portfolio of the intellectual property.

However, it has been assumed that large companies keep the knowhow in-house and do not share it with other companies or organisations. This occurs as their research scientists are not academics that are looking to publish, but professionals who want to produce products and new entities. Thus, everything is kept in-house, because the rewards in financial terms are important, whereas on the other hand an academic is pushed greatly by the university (**causal powers**) to publish, so that forces their approach to patent in a very different way. Arguably, agents at some point might share information as intermediaries, but there has to be some sort of written agreement beforehand and agreements that are both crucial and useless. They are crucial as they must be written amongst the company and the agent, because they express the spirit between them.

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

On the other hand the patents can be impractical mainly because in the small world of SMEs, nobody has the funds to pursue a legal case to the court, but having a written agreement down beforehand can identify all the things that can go wrong. In most cases, agreements SMEs write down rarely ever include the possibility of failure and what will happen in that kind of scenario, so in the worst case scenario the risk is known and will not create any kind of misbehaviour.

In an open innovation relationship, to protect what has already been accomplished, and there is at the same time a will to share and understand together, the bits of knowledge that can be put together to create a new knowledge will be beneficial and available to everyone. Now, the work of every consultants and patent attorney should be to help individuals that are directly related with the management process of the technology, to understand the risks downstream so they can make rules which are as productive as possible. When companies go so generously in open innovation it is an indication that they are desperate and do not have a strategy to cope with the fact that they are in trouble.

There are however some examples where a broker through the necessary and depended relation assisted a firm, covering all three levels:

*“The chief scientific officer of a large pharmaceutical company (Pfizer) in 2006 was asked by the USA government to create a solution for the bird flu, as at the macro level the government wanted to present themselves as strong, efficiency and caring. At the same time, in Oxford a CEO of a vaccine company was connected with the broker, thus nine months later the big pharmaceutical company acquired the small company, not only because of the concern of the government, but also because of the necessary and contingent relations of the broker. Not only did the small company sell its promising new vaccine, but it also created the necessary connection to actively and effectively exploit its portfolio of very promising candidates (mechanisms and powers)” (SME-08).*

For an SME, the reality is that the sector at the moment is facing a hard time financially with a few exceptions, and this creates a big problem for them trying to cover their own patent costs. What SMEs want to avoid is engaging in excess costs, thus they do not use consultants as the perception that exists is

based on the notion that all the expertise are in-house. Therefore any connection with external individuals is ineffective and the use of external agents is always considered as expensive in terms of having them in-house.

On the other hand, the use of competent external consultants is decreasing, and can be observed in regulatory bodies where they have a certain number of competent people around to evaluate biologics and applications but they are not enough. It has been indicated that by “*having the competence to enable and understand the whole cascade and what to do is crucial but not efficient yet*” (KB-05). It is characterised with great important at this level that everyone has to understand each other’s agenda and push things towards the middle ground which can benefit both sides.

Whereas big companies have their own in-house capabilities, small companies do not have the competencies and intellectual property to secure their position. As it has been identified, when companies grow they employ an in-house intellectual property specialist, therefore several specialist companies offer their services to companies, particularly in the biotech sector. This is mainly reported to occur because the majority of companies in the sector are small, and they have very complex intellectual property. Therefore often where intellectual property has to be licensed from other organisations to be able to have freedom to practice, the small companies go to the patent specialist for that purpose.

To identify the difficulties faced during the progress of open innovation cycle, a multi-layered level of analysis clarifies the numerous causal mechanisms which during the implementation of the innovation plan can cause any issues with individuals such as academics, SMEs and large companies and various government and trade associations.

## **7.4 The role of Biopharmaceutical associations in Open strategies**

Biopharmaceutical associations have a distinctive role as facilitators of innovation, particularly at the macro level, as they are the first line of communication between Biopharmaceutical firms that are their member and

the government agencies (MHRA). Pictured in figure 53, trade associations sit in-between Biopharmaceutical firms and regulatory bodies, in the form of bridging each other's agenda.

**Figure 53: Trade associations in the Biopharmaceutical industry**



It has been identified that on a national and international level, the trade associations can only see bluntly, so they will try to be of service even though some companies are not members, but conflict occurs when the trade organisation state that it favours its members.

In this instance it was identified that the members who can afford the membership can get larger funding and some type of revenue. Now the SMEs and the start-ups are reported that do not want to belong to an organisation, which is driven by the needs of the few, but they wish to be part of an organisation that is driven by their needs. Trade associations are seen by many as a lobbying mechanism, which are not directed in a particular way. Specifically, the ABPI is more interested in marketing products rather than in research and BIA the opposite, lobbying for their members in terms of financial support and deal making. In other words, the ABPI represents the big pharmaceutical companies and not as much for the small companies.

On the other hand it has been observed by several brokers that, “the BIA understands more the position of SMEs, but their membership fees are somewhat expensive and inefficient, because if a firm would try to calculate their return on investment of being a member of BIA it would be really difficult to do so” (KB-01/05-08). In plain words, trade associations exist to represent the interest of their members, either pharmaceutical companies, biotech

companies or diagnostic companies, as that is what they are paid to do. So automatically their core competence is to secure the interest of their members. So Industry associations at a multilevel viewpoint are seen to serve as royal knowledge brokers, as they organise several meetings, conferences and seminars, where they allow academics and industrialist to broke shoulder. Nonetheless, there are always some tensions and conflicts of interest but it is how these interests are managed that makes the difference in a trade organisation with impact. Nowadays, in a time of financial constraint and increasing regulatory hurdles, it has been acknowledged that there is a need to engage in a more constructive way with regulatory bodies, industry associations and corporate partners.

Several examples exist regarding the involvement of trade organisations, such as in personalised healthcare, as the trade associations are just one component of the process, for example the public engages in and there is a gathering of various stakeholders, but it requires skills and knowledge to bring these parties together. In doing so it was identified that:

*“The public needs to be engaged, the patients and doctors, and individuals that are engaged in personalised healthcare must come together to make it work, and it is understandable what trade associations are there to do, which is to protect the interest of their members” (KB-06.)*

It was also observed that trade organisations have an agenda and they are trying to work out what is best for the companies they represent, and quite often this is around the open innovation concept. It was stressed that running a trade organisation is not an easy job, because it requires the management (**causal powers**) of several individuals and to satisfy their needs, but realistically, it can never satisfy everyone's needs. At the end, some will have an agenda where the trade organisation tries to put it through, and others will not get their agenda through. Eventually, this sometimes creates tensions between the members, but it is up to the trade organisation to manage these tensions.

There are always different opinions regarding a decision, as agreeing on some sort of agenda that will be applied and will have the involvement of small companies with other various organisations, the large companies will not be

happy with it, as it excludes them from the process. In addition to that, there is a lot of dialogue particularly in ABPI, and there is still going to be some resistance, as some regulators do not work well with the industry, and ultimately they are there to protect the companies. When companies are authorised by the regulatory bodies it is the seal of market approval, but usually it goes back and forth before it becomes official, if it ever reaches that point.

Arguably, as brokers pointed out, the industry must get a working agenda and become regulated by making sure that they design new drugs. On this, the BIA that has regulatory meetings with MHRA at least once a year is not enough to begin with. For instance, what was identified to be the case is that:

*“BIA members and MHRA members sit down for periods of time and are trying to see what each other’s agenda is, but having meetings more than once a year will make more sense. By doing so, it will resolve more problems and ensure better communication, as they come back now with problems that could be avoided if they had better communication” (KB-02.)*

Currently even though there is a lot of dialogue around this topic, and there is still going to be some resistance, as some regulators do not work well with the industry. However, ultimately they are there to **protect** the companies’ interests and when they get authorised by the regulatory bodies; it is then a success, but this requires a lot of time and effort.

The trade organisations are getting a working agenda which is regulated by the MHRA as they make sure that new drugs are designed. The regulatory bodies have an agenda and the BIA has an agenda, but it must be worked out by communicating with each other to overcome the barriers of mutual understanding. Big companies have bigger agendas than small companies, as everyone is talking about the SMEs but large companies always have their way in the negotiations within the trade organisation. Lately it has been reported that things are improving, as a lot of aspects are going well from the SMEs point of view, as the government pushed several joint programmes for SMEs.

Whether it is pharmaceutical companies, biotech companies or diagnostic companies, trade associations are there to represent the interest of their

members, which is what they are paid to do in the first place. Therefore, automatically their position is to secure the interest of their members, but they are just one component, as the public comes in and other various stakeholders and the challenges are to successfully bring all these together. For instance, *“the public needs to be engaged, as do the patients and doctors, so several individuals must come together to make this work, so from the industry point of view the firms have to have access to patients to push things forward”* (KB-08). This has to have a clear concept in order to deliver an essence or drug, therefore what trade associations do, is to secure the interest of their members. Eventually, as the brokers identified, when all the players come together under one agenda, then that is a notion of success.

Fundamentally, trade organisations are aware of factors that affect the industry but they're pretty focused on representing the interests of their members, as they have an agenda, which it trying to work out what is best for the companies they represent, and is often within the open innovation concept. On all three levels, trade organisations are managing a lot of individuals and representatives and satisfying their needs, but it can never satisfy everyone's needs, as at the end, some companies will have an agenda where the organisation can try to put it through and others don't get their agenda through. Sometimes there are conflicts of interests with someone on the board that is not happy with the decision. So on the one hand a board member might agree on some sort of agenda that has to be applied involving small companies and other various organisations, but the large companies will not be happy with it and will try to pass their agenda instead.

Trade organisations create events to reconnect companies and individuals and they are involved in initiating connections and talks in specific areas as one of their main goals is networking, and at some point bringing in the technology strategy board where there is a call for a particular area. There is facilitation in many aspects and when the involved parties do not trust each other then it automatically creates conflicts of interest.

Effectively trade organisations are *“networking and lobbying organisations”*, as they are facilitators by helping, creating and developing the environment for open innovation. Several types of organisation promote open innovation, such

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

as incubator centres that are having a bigger role as they are closer to the individuals that are innovators in their incubator space. By doing so, incubators can easily identify how some companies could work together, by collaborating and creating the structures for the facilitation of open innovation. One of the main drivers to trade organisations is to create an environment where life science companies can do the research and development. On that, the regulatory environment and restrictions does not limit their research and can create a financial environment where companies can raise money and the funds they need to develop their projects. It is obvious that the job of trade organisations or a part of it is to create networks to assist in their process which falls within the open innovation framework. If a company could not do it by itself, that's what trade associations are for, to give value to our members and the sector as a whole.

As trade organisations work as networkers, the more open innovation goes on the more powerful the trade organisations are because they can point out to their partners that they are working together and in principle it shows the value of their network. By creating networks, trade organisations are creating a collaborative partner environment and open innovation has an important role to play. Therefore, open innovation can really help or bring additional value, and some case studies between now and then show that open innovation helped to engage with large companies such as GSK, that promote access to e-journals and introduced the collaborator to their academic collaborator. So the measurement of the value of open innovation, the scepticism and the lack of confidence is among the difficulties trade associations and organisations face during the application of open innovation practices.

Several countries are now encouraging their life science sector, and at the moment they are creating environments and tax incentives to draw the attention of companies to investing in them. The R&D incentives and tax credits are working very well in this sector, and the trade organisations lobbied for the introduction of these incentives. As there are many varieties of difficulties that companies face, such as tax, financing and funding for the sector and regulation and intellectual property when they engage in open innovation, they can be resolved not completely but to a satisfactory level for the participants. Additionally, there are other initiatives, such as the medical

research councils that create a high level of science, so the research is solid, and research councils are secure and the government has done good things in the Biopharmaceutical industry so their impact is positive.

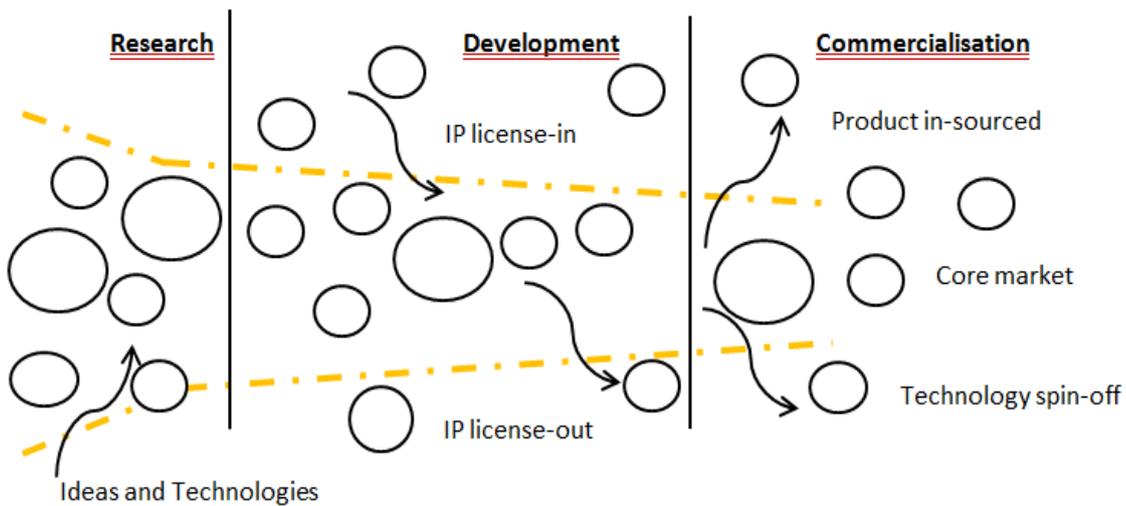
To examine the barriers during the progress of open innovation, the study explains on a multi-layered level of analysis the numerous causal mechanisms which, during the implementation of the open innovation practices, can cause any issues or barriers.

## **7.5 Barriers and setbacks during open strategies**

A number of drawbacks of the open approach were identified, during early stage research, development and marketing.

One major question of around the potential obstacles has to do with whether or not the board, which might be very traditional in their decisions, can be convinced to move in an open direction. When funding is on the table it has been acknowledged that it is taken under the clarification that the people who are working on the project have the proper requirements for the project, as the board decides when and if the project will be funded. Usually when something innovative in terms of business model is introduced to the board of directors, there is always the possibility that several constraints might arise that have to do with understanding the concept and its value for the firm or the organisation. The following figure explicitly describes the process of open innovation adoption and the possible routes a company can engage.

**Figure 54: The open innovation context process**



Source: Chesbrough, 2006, p. 3

What does seem more certain is that as soon as firms acquire external resources, they have to accept that they can be constrained and clearly the articles of association between the borrower and the lender have often written certain decisions that secure the investors position. At the same time, *“internal tension of management and leaders can occur, and if they have a particular cultural mind-set, they have to persuade the board to go with their culture. It can also be the other way around, that the board might have a very high-end approach to open innovation and may be dissatisfied with the insularity of the team, in which case they change the team”*(KB-01). This shows the importance of the early stage relationship within a firm, which is the key to a successful engagement.

The first and foremost priority is the **attitude** in any given situation, as internal functions and relations are responsible for a firm’s approach. It has been recognised by many brokers that once an inappropriate person is appointed in a significant role in the company then it becomes a barrier, because inexperience can actually damage the firm by limiting its business due to unskilful decisions. For a small company, the appointed director or scientist might at some point create structural barriers which cannot be easily overcome. Consequently, an arrangement has to be designed in a way that will secure that neither of the parties is going to benefit from the first open

innovation action, and it has to be recognised that neither is going to be benefited unless a way will be established based on the written agreement, which frees the parties from a stand-off or a hostile action. By introducing such agreements a deal shares the profits and gains 50-50 or whatever the contract states, and then after the parties can be creative and develop novel technologies and products within the collaborative space. Trust has been identified as a very strong “**buzzword**” in open innovation and it can be a barrier when the engaged parties do not trust each other.

There are factors at several levels that affect this situation positively and negatively and first of all making contacts is high on the list. “Some companies are extremely open to an approach, (such as Lilly) where their relationships with external individuals and specialist managed to complete several deals, but the channel of communication at a later stage seemed to be so bad that they did not allow any communication although there has been a proven record of successful contracts” (KB-06).

Nowadays, some of the big pharmaceutical companies have defensive mechanisms and would not allow anyone to get near them, and at the same time other companies promote their details and connections on how to contact appropriate individuals within their firm. Getting a response from the individuals that are responsible for a project within a large company is another barrier, as the waiting time is sometimes very long and even some times there is no response, which slows down the whole innovation process. Consequently, **contact**, **response** and **process** are among some of the significant barriers during open innovation practices and projects. An example of that was indicated to be “*a large company (Bayer) in animal health for animal vaccine, where every step was clarified and explained, the next steps and the duration of the project. Furthermore, they were even trying to keep the relationship on a professional level by always being accurate, which resulted in a brilliant the long-term association*” (KB-08). On this, it has been agreed that good behaviour is always a positive indicator when things are in a deal making stage. But as always, the mind-sets of the involved parties, which create the **contact attitude**, **response rate** and the **process quality**, are significant throughout the duration of the project.

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

Similarly, during university collaborative research in a consortium with academic partners, almost without exception the commercialisation of the intellectual property is complicated by internal argument because the partners argue on the percentage of work or effort they put into the development of the IP commercialisation, but arguing and agreeing is very hard to keep up with. Nonetheless, individual interests who are brought to the table, can effectively measure who did what and for how long. Negotiations of consortium agreement are a barrier, and in open innovation is de-facto, because a number of academics are sharing the IP but not effectively, as knowledge and aptitude are necessary for such deals. An example can be when a company has completed 70% of the work; it will then not be satisfied if the consortium allocates the partner with a 20% revenue contract, which is a real and significant barrier.

Now, some problems that have to be dealt with are the funding from the EU such as horizon 2020<sup>18</sup>, which is a large consortium forming open collaborations. Particularly, in framework 7 which allows up to 6 partners in a consortium, there is a lot to consider especially when one of the partners is a corporate who feels that they should have the right to deliver the commercial aspects of the new drug. It has been recognised that academics tend to overestimate their contribution, and what they do not ascertain is that a drug's development life cycle takes from 1 to 15, where the academic partners play a role from years 1 to 3 and a significant cost (£2.000.000) whereas the costs of year 3-15 is more or less fifty to hundred fold (£1.000.000.000).

At some point the firm has to realise that there has to be an equitable return on the small investment, which is not half a billion pounds, because most of the expenditure that adds value comes from the commercial partners of the development. In addition, much of the managing of open innovation has been fruitless, as the concept is beneficent but its management has been recognised deficient to date. The concept makes sense but the management is the issue, and the expectations of academics and industrial partners are always an issue,

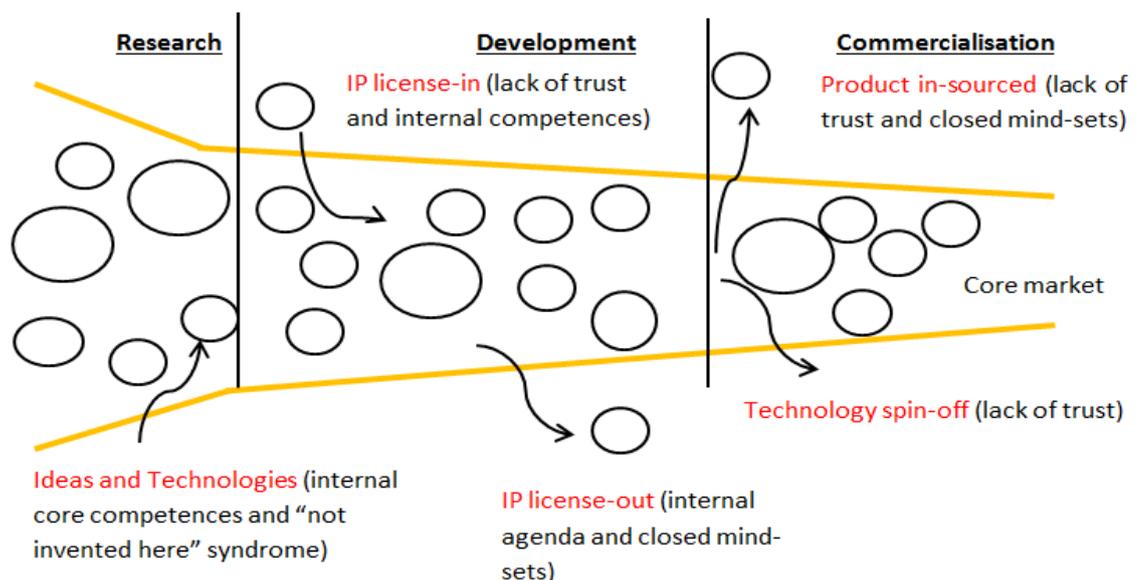
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<sup>18</sup> Horizon 2020 on Competitive Industries objective - [http://ec.europa.eu/research/horizon2020/index\\_en.cfm?pg=competitive-industry](http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=competitive-industry)

as they have not yet evolved to a maturity, as the pragmatic evaluation of appropriate returns in open project is not yet complete.

In most cases and at all three levels, the commercial agenda plays a very important role, and as far as open innovation goes there will always be limits. What everyone that is involved with open practices should understand is how to evaluate the needs of others within the open consortium. To an extent, working out to realise what the problems are and coming together and solving them, should be at the outset coming into an agreement on what everyone is going to do, and what they are going to make out of it. Whether internal issues, external issues or problems occur with collaborating with other associates, there is always a problem in that a firm or an organisation will have to face problems with in a consortium.

**Figure 55: Setbacks, difficulties and barriers under open innovation projects and processes**



Source: Chesbrough, 2006, p. 3

Skilled individuals supplying core competencies play a very important role in the Biopharmaceutical sector, as the research and development of a novel technology will not occur without experienced scientists and industry experts. Managing open and complex decisions are always a barrier, as they are related to personal mental blocks towards the open innovation concept that comes

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

from the firm itself, such as the internal management team and mind-set. There is always a good chance that open innovation can work for a company, such as the BRIC consortium, which has been set up a long time ago. In other words, the management can be the key and they are creating barriers or solutions.

Nowadays, there is an increasing understanding that open innovation can provide a benefit to companies, and there has been more open management in the Biopharmaceutical industry, but everything has a positive and a negative side. Attitude plays a very significant role, as by joining a project with a positive attitude and looking at how best to move things forward is a way of success, and on the other hand if a company engages open innovation with a negative attitude then most probably they will get nothing. Although this has always been the case, having the right attitude towards a project is a very significant factor.

Trust is a problem in any collaboration and what must be done at the beginning of every joint project is to get an agreement in place which ensures that each side is satisfied with the conditions that they are getting themselves into. It is crucial to recognise what an open collaborative project can deliver, and agreeing at the start of the project is considered both important and essential. Open innovation has a wider approach in collaborative research and development these days, as it has been recognised by other companies that working together can often develop faster and better results. Part of the challenge particularly for SMEs is that the venture capitalist that provide early financial support will probably state their own line, and do not want firms to deviate from it, which limits the possibility of open collaborating projects. This is slightly surprisingly as VCs in the technology sector have looked at it in a different way, whereas VC's in the Biopharmaceutical sector are different, partly because the time line is so much longer.

Different mind-sets in each of the three levels can create a strong barrier for open innovation to occur. In a way, academics think that they are doing open innovation all the time, with the industry thinking that they are doing it, but biotech start-ups do not seem to understand the concept and the value in the same terms. What the government wants to see is the value and the impact in

economic terms and trade associations see the value as the more they show that their network is engaging and interacting through open innovation, it shows the value of their process and progress by representing the firms of the industry. At a point it is unrealistic, as academics want to have a high end in what a pharmaceutical company will invest millions in, and on that they argue that it is their idea, but they don't recognise the risk of developing the particular technology. To make things simpler, open innovation has to be about collaboration, working together and sharing ideas, but individuals are keen on over complicating things by being insecure in terms of trusting other individuals or entities, as they push their own agenda, but they have to understand what the agenda is by opening each other's plan, and then focusing on what the problem is.

So basically in most cases, individuals either in academia or in the industry don't know what the agenda is because they don't have trust in each other. As soon as they start sharing their agenda with each other, they can actually succeed in what they came to do in the first place, which is to develop a new drug, technology and idea. Open innovation is a strong and complete concept, as it brings everything together, but the reality is that trust is a very significant aspect in every project, collaboration and business plan.

At the end of the open innovation process, if one exists, there has to be a transfer of intellectual property to one group and that might stop open innovation from happening at all because it doesn't sound truly open. At the end of the day individuals don't get to share the benefits or the spoils, as if they want to do so, they would have to endorse an agreement which identifies who gets what, which is a business development rather than open innovation. But by having a clear mind-set and a strong agenda at hand, then the option of joining open collaborative projects is in a way easier and more effective.

As with every business approach, open innovation must have a horizon for its application, and through it the study tries to capture the attitudes in terms of the duration of open strategies either on a long or a short duration.

### 7.5.1 Attitude of participants during Open Strategies

Another critical point which has become clear is that **perception, lack of confidence** and **attitude** towards open innovation in terms of “*what is in it for me*” are amongst the difficulties during open innovation strategies. Interestingly enough, academics assume that they are practicing open strategies Pharmaceutical companies are trying to do it whereas biotechnology companies do not quite understand it and part of the role of the brokers is to help them understand. In terms of the government, there isn't any specific attention focused on open innovation, as the government cares about economic impact and if open innovation has some additional value to economic impact and growth. So linking the best centres in a way that the government feels that the investment is making value is one of the predominant approaches of the government towards open innovation. There are a number of avenues available:

- It has been argued that in any company, senior executives and managers will work with academia only to the extent that it advances the company's goals in a beneficial way (Partuze et al, 2010).
- At the same time, leading an extensive site of personalities in large companies and organisations is considered to be an important factor, either in the private or public sector it is a key point of progress.
- However, sometimes the environment creates difficulties particularly when individuals are coming from different backgrounds in which they are driven by the principles by whom they work with and who pays them.
- The large trade organisations in the sector are driven by the need to lobby with the government and also by the interests of the largest companies in the sector who are often sales driven.
- For the big trade associations, their interest is around lobbying for their member, whereas the regional organisations are interested in helping with the brokering process and there are also organisations that are private and in a way they promote outside national lines to their members.

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

- By doing so, the regional organisation increase the chances of meeting the individual you need to work with in the regional context but on the downside, their size is actually very small.

The main idea of innovation is actually very rarely visible in what trade organisations do, and by looking at the UK's strategy which was produced by the government several years ago to invigorate the sector, it is actually designed to help established companies not SMEs. However this is actually a mistake as the majority of companies in the sector are SMEs. Academics are driven by their own desire which is thirst of knowledge, but it is very difficult for an academic to collaborate without publishing for a long period of time, as that can be difficult for their commercial settings. There is an encouragement of the mind-sets of individuals that work under open innovation practices but then again, core competences need to change in order to fully apprehend the opportunities open innovation can create.

When individuals encounter another party or organisation they seem to be publicly offering something and they don't necessarily realise what that organisation is driven by, so they have false expectations of how much the particular company or organisation is going to help them, whether it is the right pathway or not. It can be argued that open innovation is not widely understood in terms of why all the players in the market do what they do. Arguably, venture capitalists who fund early stage SMEs and individuals receive their funds from pension funds and big cash deposits, so if they do not meet their requests and needs then they cannot be protected against anything.

Moreover, it has been criticised that in Europe there is no commercial sense in terms of the involvement of academics with the industry, and it has been characterised as being somewhat amateur, inefficient and impractical at times. This is the case as universities argue that their policy is towards that direction, but it would never work under open strategies and in a way it shows the level of inexperience that exists in several higher educational institutes. In addition to that, a lot of universities that assist in creating spin out companies through early seed funding, desire a percentage of ownership of the company which will be non-diluted forever. This is a barrier for companies that wish to move things forward, as they cannot raise external funds to cover a potential

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

expansion based on the universities non-diluted stake in the company. It has been argued that the approach can be simplified by stating that the university will get a small percentage of an offer, which is mainly an acquisition, but the acquisition is going to be quite big.

So universities are innovating but are not very good at the development side of the innovation, thus there is the necessity, to an extent, to make their innovative programmes “*tailor made*” programme to a specific corporate niche or a specific outcome that at the end adds value in commercial offer. That is regarded by many academic partners as somewhat of a “*challenge*” to their academic freedom as academics are pretty much focused on their publications and internal R&D. On the other hand, recently there are specific deliveries in accepting a grant from the medical research office and EPSRC which forces the university to come up with an impact statement which means that the universities have to show how they can adopt the outcome of the research into corporate requirements which are later on translated into benefits for the society.

What is happening nowadays in the UK and the USA is that authorities are much better than they used to be, as for example the MHRA can have an open meeting where a company can pre-write the questions and get answers to the questions immediately and can make business decisions right after the meeting. So in this way there is no waste of time as MHRA staff can come up with very constructive feedback. Now what the government is doing is to align with what happens in academia, so in a way they can be a bit inexperienced at times, but it shows signs of improvement, but it is taking a lot of time which makes it very slow. It is politics at the government level, but it is also politics at company level and also with individuals.

An example of politics at the meso level is the reply of a large pharmaceutical company (Astra Zeneca) to an official statement of the government on infectious diseases, stating that: “*We completely agree with the direction of the government and for that reason we will focus in our oncology project*” (KB-08), but there is no connection with oncology and infectious diseases. So there was no relation to the actual proposal, but it was more of a public statement which actually had a negative impact as it was moving in a different direction. Then, a

couple of days later the same company (Astra Zeneca) came out and said that *“part of our on-going view is to “de-prioritise” infectious diseases”* (KB-08), so effectively they were going in the wrong direction to what the government was saying. So the **public** understand there is a problem, the chief medical officer of the **government** is shouting now for that, and the **CEO** of one of the biggest pharmaceutical companies (GSK) is saying is that they have to do something about the particular disease problem, although the company he represents is not doing enough right now. So effectively the big pharmaceutical companies are the ones that the government talks to initially for collaborative work, as they control the largest investment funds in the industry, as they have the necessary and contingent relations with government officials to drive these priorities.

In all fairness it has been acknowledged that it is unlikely to achieve an open collaborative project with academics as they want to have a high end in what a pharmaceutical company will invest millions in. To that, academics argue that it is their notion and knowledge that delivered a potential candidate, but they don't recognise the risk of developing the particular technology. As open innovation has to be about collaboration, working together and sharing ideas, individuals keen on over complicating things by being insecure in trusting other individuals or entities, such as having individuals' agenda, must understand what the agenda is by opening each other's plan, and then they can focus on what the problem is. It has been identified that in most cases academics don't know what the agenda is because they don't have trust in each other. As soon as the sharing of agendas' commences, there is the possibility of actual success, which is the development of a new drug, technology or idea. Open innovation is an attractive concept, as it brings everything together, but the reality is that individuals are not keen on trusting each other.

The difficulties come down to the knowledge developed within the open partnership and how that is allocated from an intellectual property point of view. Some of the open innovation projects have started in the spirit of full openness, but it might come down to the fact that for some parts that require more work there is an argument over who does what and for how long, which is the biggest challenge in open arrangements; how open innovation

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

progresses to a stage where individuals come in, get the agreement in place and set it up in a smart way. There has been a lot of learning examples and settings of smart property agreements where the intellectual property is shared in a correctly proportionate way. It might not necessarily be an innovation as it is translating the idea into a product which is often a key step as ideas are not products, but potential products under skilful development:

- I. A significant difficulty or challenge is to make sure that the agreements are set at the beginning of the project before the progress has gone too far, as it is the key to controlling collaborative projects.
- II. If the space in which the collaborative project has been defined, it is clear what the work is, known what contribution is and what the reward would be at the end, if the project is successful in terms of revenue generation.
- III. A problem lies with some universities either because they are restricted on the way their IP is set out, which is hard sometimes to the detriment of the projects progress.
- IV. Universities have to be more open and recognise that it may or may not be as much up front, but it might be more successful in the long-term or it will keep a stream of revenues for a longer period of time.

Individuals such as academics were stressed to be “looking into more long-term obligations and it has been criticised not just in biotech but also in pharmaceuticals and cross disciplines within universities, as individuals say that they are not going to deal with them unless there is a large payment up front, so the risk is not worth taking” (KB-01). Large Biopharmaceuticals are most likely willing to reward individuals when the property will bring in revenue. Lately there is pressure in several ways, as universities realise that their revenue from intellectual property is falling. Now, Individuals are not taking the progress forward and researchers in universities are aggressive, therefore there is pressure on the individuals who are developing the technology in the university, meaning the academic himself, can put things forward when the prospective is better.

Academics tend to work for very conservative organisations, and to some extent the concept of open innovation is not easy for them to grasp. Either

open innovation exists and it is a very important concept or it is something that cannot work and cannot generate value. It has been considered that open innovation is required at this point in the industry, but open innovation will not work when individuals from outside are asking what is in it for them, as it creates a dichotomy between the side that wishes to engage in open innovation and the other side that considers its own agenda above all. It has been argued that academics might be the actual barrier to open innovation as several academics argue that they already partake in open innovation, but the truth is different because they are not that open. It is also considered that academics believe that after input the process of development and marketing is easy. For example, if an unknown molecule is found, then the belief is that surely the fermentation of the molecule is a straightforward industrial process, where by just turning the handle the magic comes, which is far from the truth.

Additionally, there is an obligation to their employer (universities) not just to give away the IP immediately, which is an obstacle to openness and they certainly have a narrow view of competing technology when they are trying to do something that is not just their science. So if academics were to build the company, it would not be able to start as their approach would be unlikely to start and at the same time their threat to open innovation is that they will be narrow in regarding collaborators as their peers, and if there were not in the same field they would think less of them or they would think that there is no way that they could interact. Although that was the case, it is decreasing in magnitude nowadays, but the attitude has not gone completely.

Trade organisations play a significant role in the shape and process of the Biopharmaceutical industry as they act as a body that negotiates on behalf of its members from the Biopharmaceutical industry, for legal consultation requirements including the pricing scheme for medicines<sup>19</sup> and the promotion of the industry<sup>20</sup>.

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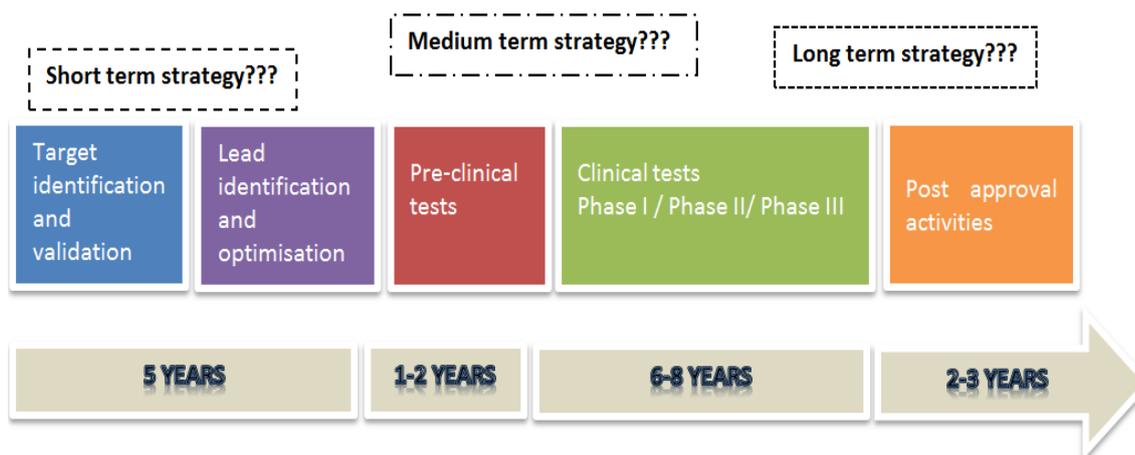
<sup>19</sup> Association of the British Pharmaceutical Industry - <http://www.abpi.org.uk/about-us/Pages/default.aspx>

<sup>20</sup> BioIndustry Association - <http://www.bioindustry.org/about/>

## 7.6 Prospect of the open innovation approach

A long-term commitment is desirable in the Biopharmaceutical industry, as most firms and organisations have a full commercial approach towards their innovative projects. As figure 56 points out, a strategic approach can be short, medium or long-term, as in the Biopharmaceutical industry an exit opportunity might come at any time.

**Figure 56: Pharmaceutical process duration and strategy**



It is very significant for a company that is seriously looking to adopt open innovation, to implement it on a long-term horizon. It has been identified that individuals that drive the open innovation approach are doing so to avoid the mistake which everyone is making, by putting everyone's minds together on the table and getting a better solution. As is has to be guided from the top management until the last scientist, the top management such as a CEO should be responsible for its adoption, and based on that reality the CEO should and must understand what that strategy is. In many cases, what the reality is are the decisions of the CEO who is in charge.

- The approach towards open innovation has to be a long-term process as the applications of Biopharmaceutical R&D process need to be a long-term pattern.

For long-term success there has to be an incentive to the employees to participate in the long-term open projects, and the ability to measure the open innovation and reward them accordingly.

The industry although having adopted open practices, is only making baby steps toward opening up clinical trial data, and several deals between big academia and pharmaceutical companies. Hardly any of them have deals with more than one company, so what is actually happening is open exclusivity or a closed innovation approach, which is transmitting downwards in the value chain from the pharmaceutical company towards the owner of the property. This shows that in a sense, the individuals that are responsible for such actions either are CEOs, academics or policy makers do not have a clear understanding of what they do and have no clear concept, as it requires an open channel between a company and a university in specific research areas. So effectively they do not partake in open innovation. Now the pharmaceutical industry cares about innovation because the fact that their R&D budget is minimising is very concerning, and open innovation happens because it will now be one of the few ways of doing innovation. This is because VCs and large Biopharmaceuticals have stopped contributing “the big money” to carry out R&D as R&D is seen as a cost rather than an investment.

More and more the approach of open collaborative innovation is seen as a long-term approach, as the difficulties have to be overcome through external partners, and in a long product development process as the Biopharmaceutical, the adoption or application of such strategies have to have a long application horizon. It has been criticised that to get open innovation to work it is going to take recognition of its potential use, which might take years to come through. An example of this approach is a large Biopharmaceutical firm (GSK) who went open a while ago, but still have a lot of backdated projects for internal use, which they make a lot of resources.

## **7.7 Conclusions on the Knowledge Broker Perspective**

From the foregoing analysis, open innovation requires several applicable skills, and these skills may be differing for short-term projects compared with long-term strategies. These skills are either complementary or executed separately,

particularly in the early stage projects and in view of the various cross industry challenges they face. An example of short-term open strategies was identified by a broker to be *“the automotive industry, with the manufacturing technology centre in Coventry, where they brought manufacturers such as Rolls-Royce, and they realise that the aerospace sector and the car manufacture sector were looking at similar challenges in their manufacturing process”* (KB-03). Therefore, by looking at problems in open collaboration, they were able to assess several aspects and at the end they have addressed their challenges, thus everyone learned from these challenges. Nonetheless, brokers identified that open approaches were utilised in the past, not in such scale as now, but nevertheless open (Latvian institute of organic synthesis and HIV initiative by the FDA in 1987).

It has been recognised that the Biopharmaceutical industry is learning and adopting new models by observing how other industries are adopting open innovation processes; they are now looking to replicate this both on a larger and smaller scale. It has been advocated that SMEs and large companies can benefit from the size of open innovation. There is a trend in this industry in going open, and there are examples that stretch back for decades, known as the pre-competitive work of the past. This movement has to develop further, partly because it is a driver for the big pharmaceutical companies' pipeline which is not as strong as it used to be (Munos, 2009, p. 959). This means that there is the need to pull ideas together and the need to seek products and get these products from biotech companies and from academia.

Open innovation has several applicable time scales; in the long-term it will show the impact innovation had in new therapies and patient benefit; and in the short-term it will show the process was initiated. It was stressed that the language everybody uses in the industry is *“faster and better or cheaper”*, so what does a new product do; is it faster, is it better or did it make the process cheaper? The industry is just starting on its journey, and there is going to be a mixture of both short and long-term approaches. Furthermore, it has been acknowledged that the approach can also work *“on short-term projects and long-term strategies, as more companies should be looking to work in open innovation environments, particularly in the early stage projects and also across the industry to evaluate the challenges they all face”* (SME-01/08). This

works as a form of hybrid approach, during the early research and development processes as well as later clinical testing and marketing stages.

There is a need to show that open innovation works, and in the short-term it will not just be about the discovery of a new drug, but also about how it helped to move the process forward. As the product development process is lengthy, these benefits can be viewed in a horizon of 15 years from now. At present the long-term approach is going to be about time, whether a drug is an improvement on an existing one, and if its better and how it improved the patient experience. It has been stressed that *“companies are finding that if they work with external links it can find ways of overcoming the hurdles and regulations”* (KB-07), thus open strategies are strongly suggested to have long-term applications.

Thus, the open innovation agenda will be changing, evolving and developing as it is relatively new, so in all and strictly speaking, open innovation is more like:

*“A contact sport and the more it is exercised the more the chance is to say that it has been done differently and made better”* (KB-06).

Chapter 8 consists of the third part of analysis from the responses of the senior management of large Biopharmaceutical firms, through a survey questionnaire. The sample was identified from the interviews with knowledge brokers and industry specialists, who could give appropriate insights to the study by identifying the why and how open strategies and collaborations exist under the open umbrella. In doing so, the study utilised an online survey that was directed at senior managers and CEOs from large Biopharmaceutical companies. The survey was developed to cover the following aspects, based on their action strategy and open strategy.

- Action strategy and innovative approaches
- Collaborative processes
- Research and development capabilities
- In-outsourcing activities
- In-out licencing
- Intellectual property
- Engagement with brokers and agents

## Chapter 7 - Position and the Role of Knowledge Brokers in Open innovation

- Satisfaction with the current – new strategy

## 8. Open innovation in Large Biopharmaceuticals

Since its introduction, open innovation has been focused mainly on large firms and multinational corporations who are the early adopters of open innovation (Chesbrough, 2003a; Chesbrough et al, 2006; Huizingh, 2011, p. 4). Based on the fact that large firms are the early adopters of open strategies, the research concentrated on large Biopharmaceutical firms to capture their attitude towards the adoption of open innovation through a qualitative online survey.

As electronic surveys are attracting the interest of a population due to their methodological and economic reasons, a large and representative number of a population sample can be reached without difficulty (Cook et al, 2000). Several studies in open innovation have utilised a survey method, and amongst them are Van der Meer (2007) where he used a survey to identify open innovation practices in Dutch companies, Lichtenthaler (2008) who evaluated the adoption of the open innovation paradigm across industries and Van de Vrande et al (2009) that analysed the trends, motives and management challenges of SMEs with regards to open innovation. Given the rising utilisation of surveys for the investigation of the open innovation concept, the study utilises an online survey that comprises of structured questions, designed to provide specific insights concerning the approach of large Biopharmaceutical firms on open innovation, by identifying the opportunities it creates and the barriers the firms face during the application of such strategies.

It has been argued that when open strategies are adopted different management styles are required, from the early stages of the research to the entrepreneurial attitude during the early phase of commercialisation, and eventually to a more *“risk-adverse mind-set”* once the commercial aspect has been fully developed (Kirschbaum, 2005, p. 24). In doing so, firms usually employ individuals with high skills and knowledge in the Biopharmaceutical industry, as well as a strong entrepreneurial sense as they will be responsible of the management of the firms budget and development projects. Therefore, the study was aimed towards individuals that currently have a significant role in the management process, such as CEOs and R&D directors within large

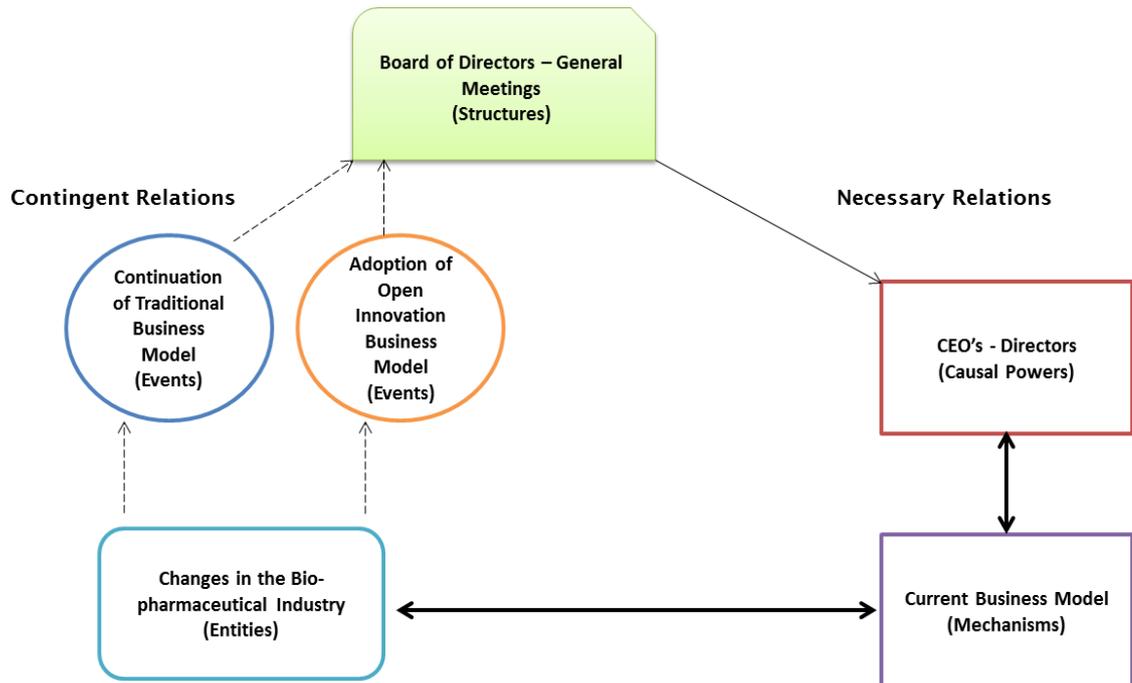
Biopharmaceutical organisations and firms. The sample consisted of 42 questions, where 5 were related to the firm's specifics, 17 were assessing the approach of large firms towards their innovation strategy and 20 questions were aimed at exploring whether their involvement with open innovation strategies and approaches is successful.

The focus of the study is to understand the concept of open innovation in the Biopharmaceutical sector, by aiming at specific entities (CEOs -Directors) that are linked to the processes of large Biopharmaceutical firms. The approach consists of enquiries that capture the strategic decisions, collaborating procedures, intellectual property structure and management of the firms (including individuals and entities such as academics, firms, institutions and government organisations).

The study identified why and how large Biopharmaceuticals firms interact with various individuals, groups, firms and organisations on a multi-layered perspective under open innovation arrangements, and how large Biopharmaceuticals firms relate their research and development activities to open collaborative projects. Furthermore, the study revealed the circumstances (on a firm and context related level) that influence innovation amongst firms in the sector and how much the circumstances influence open innovation amongst firms in the Biopharmaceutical sector.

The study adopted a critical realist approach which allowed us to explore the causal mechanisms of specific entities and agents, which are responsible in developing and executing a particular strategic decision (Sayer, 1992). Figure 57 identifies how reality exists and under which circumstances open innovation can be considered as an approach, critical realism through retroductive reasoning can give specific answers and detect how and why particular incidences occur.

**Figure 57: Critical realist view of Strategy Process in Large Biopharmaceuticals**



Adopted from Sayer, 1992, p. 93

To access information from the senior management of large Biopharmaceutical firms and organisations, the study utilised a purposive sample that enabled us to use a selection of individuals that are best empowered to answer our research questions and objectives (Saunders et al, 2009, p. 237). It has been argued (Marshall, 1996, p. 523) that the use of a purposive sample is a more logical strategy than the simple demographic stratification of epidemiological studies and due to the characteristics of the sample, variables such as age, gender and social class are not important, as the main and common characteristic of the sample is the working status, which is what drives the use of the purposive sample.

## 8.1 Studying open innovation in large Biopharmaceuticals

The sample population was called upon to complete the online survey based on the recommendations of knowledge brokers and industry experts during

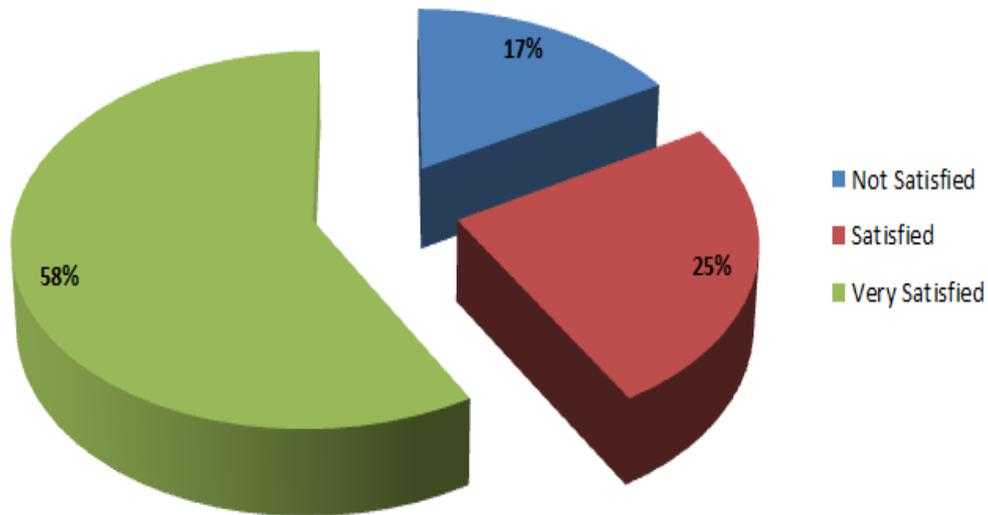
their interview process. From the commendations, the survey was focused only on the top management level of large firms and organisations, as the study aims to trace the reasons and causal mechanisms behind the adoption of open innovation business models and strategies. To date, the study achieved 12 responses from CEOs, directors of R&D operations and programme managers who at the moment of the survey were employed by large Biopharmaceutical firms and organisations.

The sample consisted of 5 CEOs in large Biopharmaceutical firms, 1 president of a Biopharmaceutical association; 3 directors of large Biopharmaceutical firms; 2 research fellows in open innovation projects lead by the MRC and the head of R&D operations of a large Biopharmaceutical organisation. Based on their position, the individuals from the sample can explicitly describe and explain why particular decisions are made when a firm is engaging in its current strategy and whether open innovation is considered or was considered an alternative business approach. Given the circumstances where open innovation was exercised, the study evaluates what opportunities it creates, what kind of barriers the firm faces during the application of open strategies and how open innovation is actually perceived by the company.

Initial enquiries concerning the details of the respondents showed that 7 out of 12 are working at companies with more than 250 people personnel, 2 work in firms that have from 50-249 and 3 in firms with less than 50. This gives diversity to our sample, as some organisations that might not be by definition large as they employ less than 250 people, are a significant contribution nonetheless, as they work in organisations closely linked with big Biopharmaceutical firms.

### **8.1.1 Components of the innovation process**

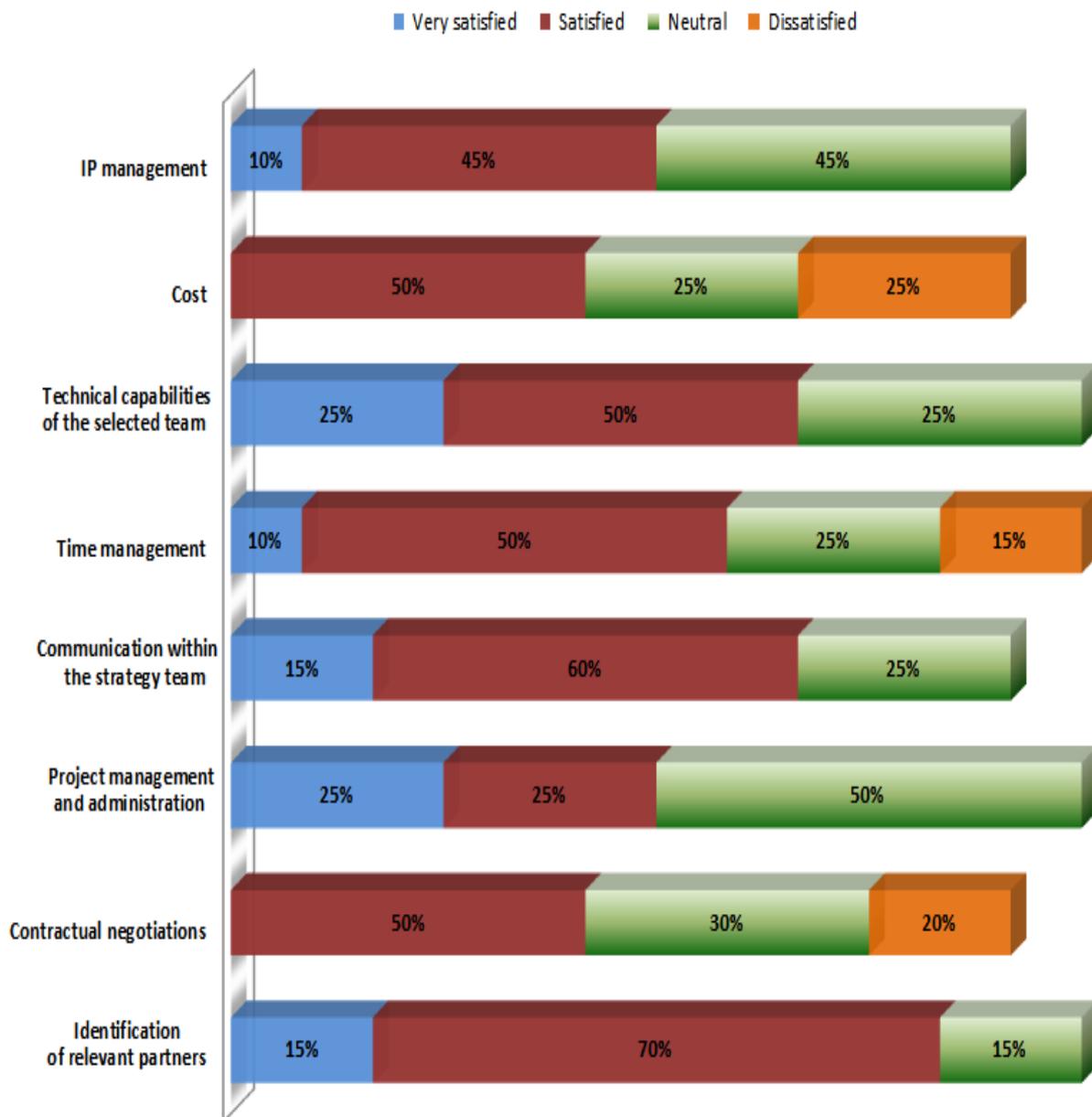
To evaluate the ability of the firms and organisations in terms of their current strategic approach to innovation, the study prepared a series of questions as regards to their approach in terms of value creation and business development. To access the results of the development of the innovation business strategy, the study examined how satisfied the specific individuals are with the business strategy of the firm they represent.

**Figure 58: Satisfaction with the current business strategy**

Nearly all of the senior management respondents of large firms and organisations as figure 58 identifies, have a positive attitude concerning their business strategy, and at the same time they value that the phase of the current progress of the firm they represent is on the right track. The majority of responses vary from satisfied (25%) to very satisfy (58%) which leads the study to investigate the specific processes that pleased or dissatisfied the people who hold high places within these particular Biopharmaceutical firms. It is clear that the objectives in large Biopharmaceutical firms are pre-determined by the annual and monthly senior executive meetings, in which every senior management participate and effectively improve the company's business approach and process.

The study captures in the inter-firm level how the current business approach of large firms and organisations is evaluated, and how they meet their expectations during the various stages from the early research to the development and eventually the market of the product. This aspect pictured in figure 59 reveals the levels of contentment of senior management in each approach of the firm's business cycle.

**Figure 59: Satisfaction levels during the assignment of a project**



Considering each major contributory component in turn:

**1. IP management**

It is clear from this study that although a big proportion of respondents (55%) have a positive attitude towards IP management, a very significant percentage (45%) of respondents has a neutral view concerning the management and control of IP. In several cases, the intellectual property is always a feature in which not only large firms and organisations, but also SMEs and individuals are

highly concerned, as not only are they protective towards their IP, but they are also defensive in sharing aspects of their novel technologies.

## **2. Cost**

In terms of cost, the majority of participants (73%) have a positive approach towards their cost management, but nonetheless a significant number of respondents (27%) have a negative viewpoint. This has been identified to be the case as in several instances the cost of the project is over budget, which is a barrier towards the development of a new and novel technology. In most cases, the costs are pre-determined, thus the project can be covered, although that is not always the situation.

## **3. Technical capabilities of the selected team**

Clearly, the technical capabilities of a selected team have a positive impact (66.66%), as they utilise the accurate people for the job. For large Biopharmaceutical firms', it is vital to employ the best scientists available in the industry. At the same time a significant proportion of respondents (36%) have a neutral approach towards the technical capabilities of the selected firm, as the outcome and the process from time to time are not desirable.

## **4. Time management**

In terms of time management, the vast majority of firms (83%) have identified a positive attitude of the time management of their current business model. In utmost cases, if a project is completed within the specific timeframe, then the team can be rewarded on a personal level. On the other hand, a small number of respondents (17%) indicated dissatisfaction with the time management of the current strategy, which is accredited on the case when the complexity and specifications of a project require more attention and additional time, creating a negative effect.

## **5. Communication within the strategy team**

Arguably, the strategy team has a positive impact for the firm, as when channels of communication are used correctly it is an indication of successful co-existence, and an aspect that was repeatedly stressed as being a significant

element in every firm's agenda. Simultaneously, a noteworthy proportion of respondents (27%) have a neutral view, as sometimes networks of communications don't work, and this leads to misunderstanding on all related sides.

### **6. Project management and administration**

Regarding project management and administrative support, there is both a positive and neutral viewpoint, as several projects face significant barriers when they are not completed at the end of their predetermined progress, or even abandoned in some cases. At the same time, on some occasions the administrative support is limited or even non-existing, as when there are a limited number of individuals responsible for the support of more than one project at the same time it can have negative consequences.

### **7. Contractual negotiations**

As partnering identification has a strong influence on almost every organisation, not surprisingly the contractual negotiations have a strong and positive effect with the majority of organisations (75%). At the same time, an important proportion (25%) nonetheless has a negative view of their contractual negotiations, which can be found in a case where the exchanged agendas do not match. It has been stressed with the highest importance that in a negotiation there has to be a mutual understanding, but in some cases, the individuals handling the negotiations are very protective as they stick to their approach rather than preparing and creating a common ground.

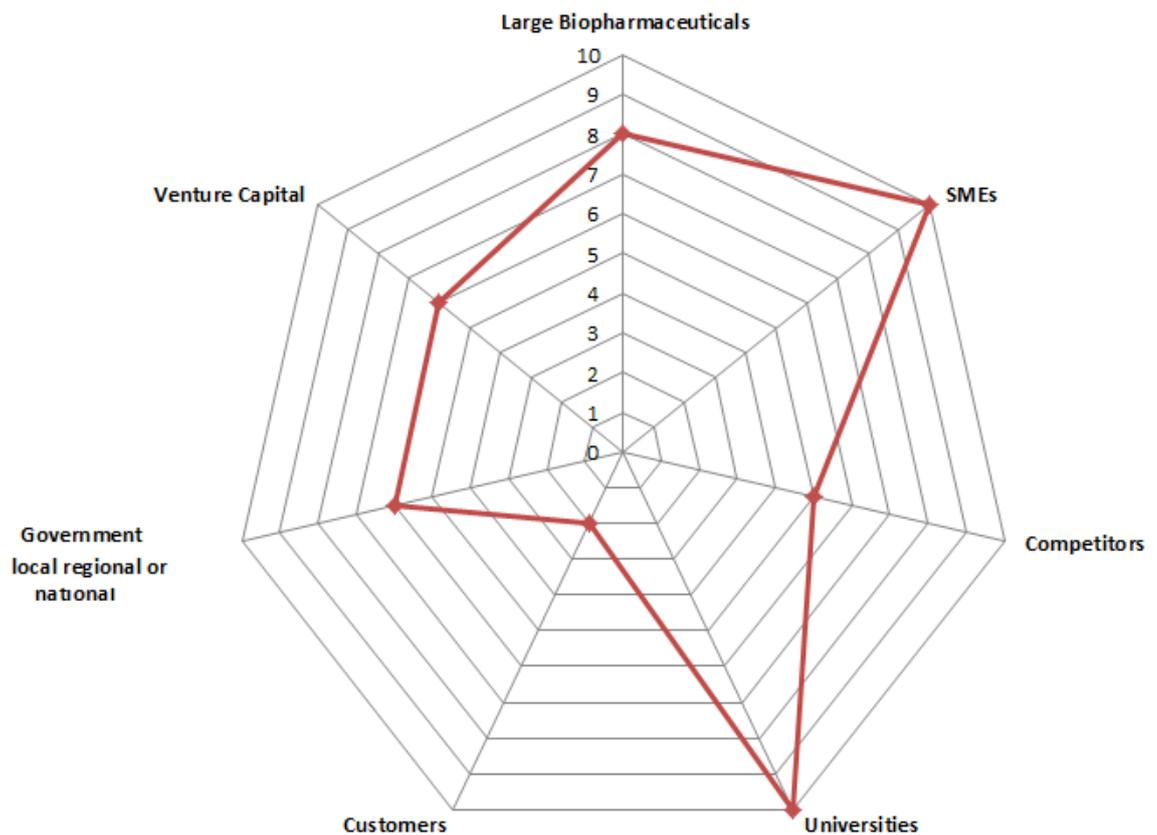
### **8. Identification of partners**

The survey identified a strong emphasis by large companies and corporations that partnering with the appropriate organisations and individuals, works as an outside help that move their current projects forward. The vast majority (83%) of the respondents stated a satisfactory to very satisfactory attitude, while the rest (17%) had a neutral view, which shows that for some organisations, partnering is not considered a significant feature of their business approach.

To assess the ability of large Biopharmaceutical firms and organisations towards network creation, the study evaluates their approach in terms of

creating and developing networks, and whether that will give them access to external ideas and resources. The study assessed the progress of their action strategy, and identified if the organisations created any networks with various external resources. All participating individuals responded positively, with only a small number responding negatively, which means that only one organisation preferred the traditional self-developing model. Figure 60 clearly illustrates with which of the following groups the organisation and the respondents actively collaborate in their innovation networks.

**Figure 60: Distribution of collaborations and networks under open arrangements**



Evidently, large organisations have very strong ties with firms and organisations, as they are seeking to incorporate outside sourced technologies and ideas. From the scatter graph, it is evident that there is a strong collaborative effort with universities and SMEs, as traditionally, large firms and organisations are on the search to acquire technologies and ideas that exist outside of the boundaries of their organisation. This is done with the use of

internal and external individuals who have the *necessary* and *contingent relations* to create *tensions* and *arrangements* between two parties or more. Moreover, venture capitals and competitor firms are seen to be among the partners large organisations engage with, either for the *necessity* of developing a competitive NME with their “*rivals*” or to actually acquire a technology from venture capitals. Acquiring IP and technologies from VCs is usually a novelty that originates from funding early start-ups and SMEs who try to create exit strategies for their investments, as VCs have been reported to support early-stage high risk investments (Sahlman, 1990).

The survey also identified that large organisations work with each other, either to overcome common difficulties or in a form of governmental contracts which requires the existence of big Biopharmaceutical players. Government organisations on a national and international level are promoting collaborative joint agreements, as it is understood that the more partners in one project, the higher the possibility is to deliver successful results. To this, the MRC and BBSRC have made the necessary arrangements to take in its investments both SMEs and large Biopharmaceuticals in the form of necessary and dependant relations.

It seems to be widely agreed that the use of partnerships and networks has a positive effect in large organisations, as they are seen not only as a way of increasing their funding opportunities, but as a way in which they can support their efficiency to government agencies through particular government backed projects. “*Collaborations for IP improvement, R&D efficiency and R&D diversification*” are effectively identified as being amongst the priorities of large organisations when they engage themselves in such joint agreements, as it is essential for them to “*identify the low hanging fruit*” (LF-12), before entering into such projects.

Senior managers from large companies observed that in many cases, the organisation encountered “*gatekeepers – knowledge brokers*” during its action strategy, as they are individuals who control access to offers or to key decision researchers. Under joint arrangements, these individuals thought their *contingent* and *necessary relations* create bridges of communication and in

many cases co-operation or technological acquirement. More specifically, knowledge brokers through their agendas can deliver:

- Access to contracts
- New and novel technologies
- Funds
- Skilled individuals

All of which are vital components of the continuation of the organisation's innovative performance.

To capture the barriers and setbacks large firms and organisations face during the application of their development strategy, the study identifies the vast majority of organisations during:

- Research and development process

These are issues that are linked with the core activities of the organisations, as they all have research facilities and laboratories.

- Legislation

It is always seen as an issue for Biopharmaceutical firms, as they have to comply with extensive and resource-draining requirements and legalities, an aspect familiar with any Biopharmaceutical firm.

- Internal capabilities of the partner

Even though they collaborative in an extensive way, partners are sometimes a setback, particularly when they are not producing the expected results.

- IP management

In collaborative agreements, issues related to the IP arise, particularly when the partners disagree on the effort level that each put in the joint project.

### **8.1.2 Open innovation Approach across Big Biopharmaceuticals**

To evaluate the effect of open innovation in large firms and organisations, the study focuses on capturing the understanding of the participants in terms of

the definition of open innovation, the engagement with open strategies and the overall contribution of openness for their organisation.

The study identified that:

- I. The majority of senior officers in large Biopharmaceutical firms and organisations (90%) are aware of the open term.

With the exception of one respondent who showed unawareness concerning the open innovation term, the rest identified awareness concerning the open innovation concept.

- II. There is a variation in the understanding of the concept.

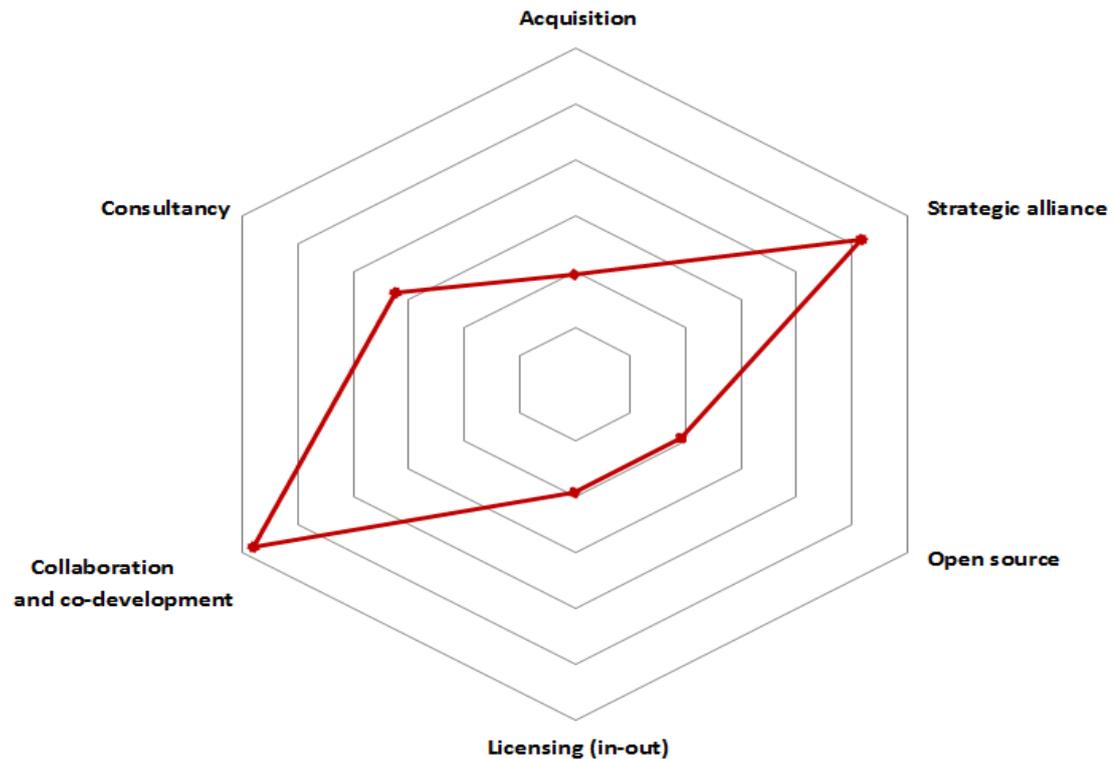
The respondents stressed that the use of open innovation is to obtain new people in the organisation to act as consultants and to help with a specific problem that cannot be solved internally.

- III. Collaborative efforts exist with a number of groups, firms and individuals.

Senior managers from large Biopharmaceuticals have identified that collaborations exist outside the organisation on projects designed for mutual gains, and it is particularly used as a form of out-licensing and in-licensing of intellectual property.

As a definition of open innovation is the use of purposive inflows and outflows of knowledge to accelerate innovation (Chesbrough, 2003), 83% of the respondents are utilising open strategies during their business models, whereas the rest (17% didn't yet have the opportunity to engage themselves in open strategies. According to figure 61, the study identified that there is a variety of open approaches in large firms and organisations.

**Figure 61: Variation of openness in large organisations**



Evidently, large firms and organisations are exercising open models in the form of collaborative agreement and co-development process. This happens mainly because:

**I. Many technologies are aligning with internal capabilities.**

Many of the outside technologies can substantially enhance their position outside of the boundaries of the organisations.

**II. Strategic alliances**

They are seen by large organisations as forms of openness and collaborative joint developments, which in many cases are driven by government organisations.

**III. Acquisition - licensing (in and out) and open source.**

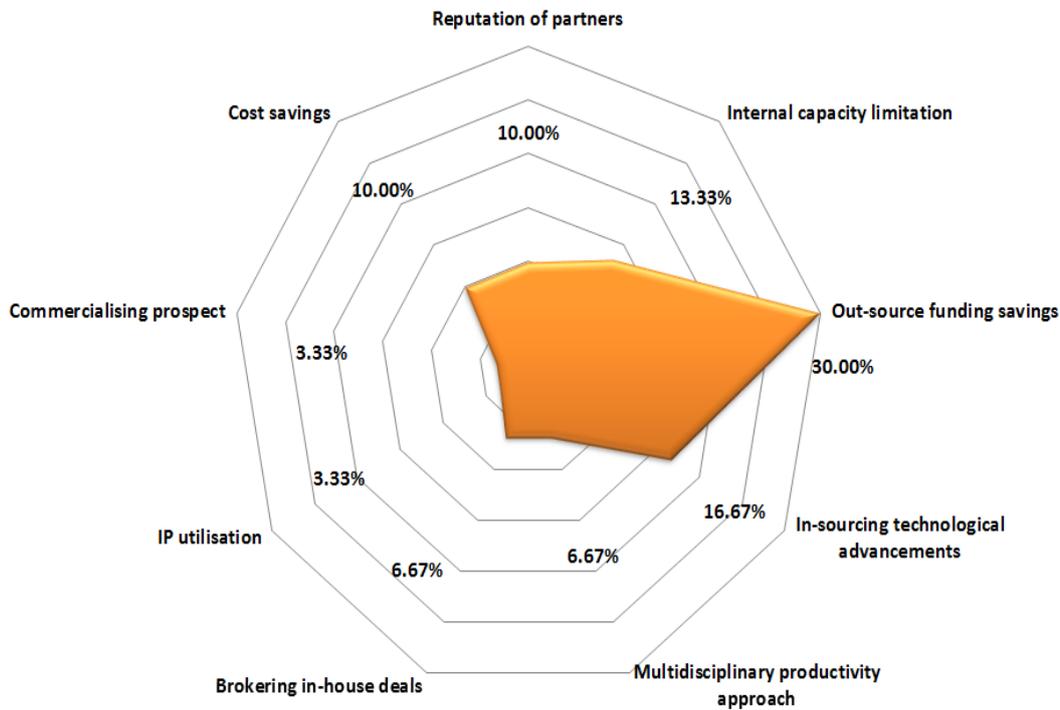
Acquisitions are seen by senior managers as points of openness for large organisations.

**IV. Consultancy.**

Consultancy is seen as a form of open involvement, as it entails of the use of particular individuals who through their skills bridge specific problems to particular solutions.

Figure 62, categorises the reasons in which senior executives of large Biopharmaceuticals engage in open innovation practices.

**Figure 62: Motives for open innovation engagement**



Clearly, internal capacities are inefficient at times to carry out the work, so a large firm throughout their necessary relations are exercising open strategies which can be traced on the multi-layered level. From the survey, senior managers identified that large organisations are utilising the assistance of “*academic partners*” who have previously established a reputation for their skills and can be seen as an arrangement of mutual exchange. Large Biopharmaceutical firms direct their attention to reputable academic groups and individuals who have a proven record of technological novelties.

In the same way, large firms openly collaborate with other various firms or organisations in the form of mutual collaborative effort to jointly develop a novel technology. These collaborations with external partners are brought by government agencies, on a national and international level in an attempt to

expand the research and development of new or existing technologies. These relations occur, when the organisations consider outsourcing their internal expertise as a form of saving funds, as the continuation of the development of a project can reduce the internal costs significantly. Moreover, by adopting open strategies, the participants indicated that they can bring new ideas into a project which can be beneficial as a different approach might as well be the next best thing.

It is believed that a multidisciplinary approach can produce successful productivity, as two or more parties can develop a novel technology faster and less costly than internally. In addition to that, an open strategy can create revenues as firms can act as an intermediate to support and facilitate open innovation in the form of arrangement making. By doing so, firms enable the utilisation of any IP that can be introduced and produced into other non-competing markets and identifying that it is a likelihood of commercialising the firm's ideas. An important factor when firms go into open strategies is cost saving, as it can *“significantly reduce several internal activities by opening the doors to external and skilled individuals, organisations and government agencies”*(LF-05).

Importantly, before the organisations made the decision to engage with open innovation, there were several concerns and reservations. Particular issues were identified to be:

- **IP**

It is among the main concern point of nearly every organisation, as the sharing process of any vital information is a risk that firms and organisations in the Biopharmaceutical industry don't want to take.

- **Skilled individuals**

The ability to find the right people to be involved in open strategies was a significant concern, as in open project, there is not much trust at the beginning, as it has been identified that every side goes into collaboration with an agenda rather than an open hand.

- **Project management and administration**

In the same way, such challenges were always seen as a huge concern, not only in open project, but also internally, as it is a gamble where and if internal or external management can deliver the promise, and whether there is enough administrative support, which is a barrier in any project.

- **Time constrains**

It is seen as significant reservation, as when collaborative agreements occur, there is no control over the time in which the partner can finish the designated work.

- **Cultural differences**

Even though might occur when two or more large firms and organisations work together, the respondents don't have a huge concern over the cultural differences, as they are UK based, and in addition are experienced in managing people from different cultural backgrounds. Similarly, cost is not an issue prior to open innovation adoption, as there is the belief that as soon as the project engages, all the parties will contribute and the actual cost will be reduced.

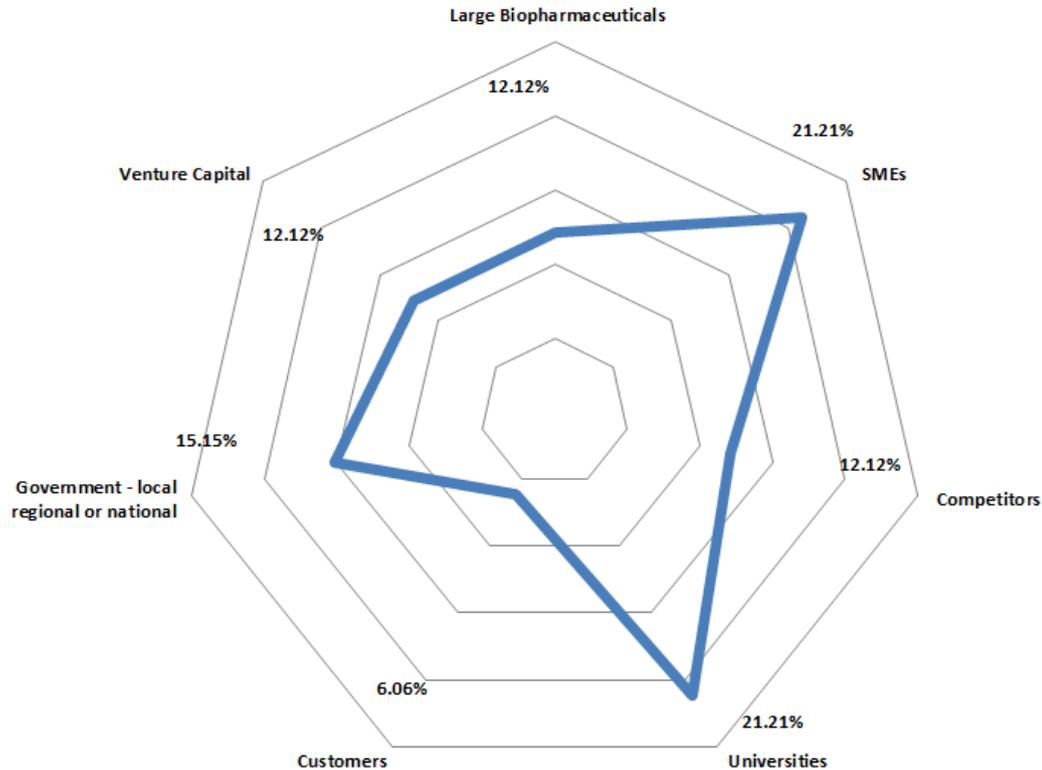
To assess the influence of open innovation in large firms and organisations, the study investigates the engagement of the participants in terms of networking, and how successful or effective they are for the specific organisations.

Evidently, only a small proportion of the respondents are not engaging in network creation (10%), and it has been identified that it occurs due to the fact that they did not have the opportunity to do so at that moment. Networks exist at all three levels:

- a. Customer interaction can create the necessary inputs.
- b. Joint programme collaborations with SMEs, large Biopharmaceuticals, industry competitors, venture capitalists and universities are a great source of outside sourced technologies.
- c. Government on a local, regional, national and international level is pushing large organisations into open strategic arrangements.

The study in figure 63 clearly illustrates the collaborative efforts in large Biopharmaceutical firms and organisations during open innovation projects.

**Figure 63: Networks spatiality of large Biopharmaceuticals**



The respondents clearly identified how important SMEs and universities are for large firms and organisations, as they are seen as a main source of IP, as traditionally they have been perceived as the basis for novel technical and technological novelties. Similarly, the government plays a significant role in open strategies, as they support such projects particularly through the MRC and the NHS. Although there is not much influence from customers and users of technologies from large Biopharmaceutical firms, it is still considered as a network expansion during open strategies. On the other hand, venture capitalists and competitors of large Biopharmaceutical firms have been seen as significant elements of open strategies, as VC's are funders of early pharmaceutical research, and competitors can feel the potential gaps under the open umbrella.

When open innovation occurs, there is likelihood that tensions will be created both internally and externally (Lee et al. 2010). The study assesses the

possibility that barriers might occur when open innovation strategies are exercised, and identifies how and why such barriers happen. From the survey, the study identified that **67%** of the respondents have and are facing some problems during their open project, which are illustrated in figure 64.

**Figure 64: Barriers and setbacks during open projects**



Clearly, with the multi-layered approach, the study identified six major factors that are seen as potential barriers during the application of open practices:

### **1. Partners**

They have always been seen as a concern, as they can de-stabilise a situation with their causal powers, particularly when they come into the project with a closed hand and a personal agenda. It has been previously stressed that when firms and organisations enter in open projects, there is a high possibility of mistrust at the beginning of the project, but can later on be resolved through successful and appropriate management.

### **2. Internal processes**

During the research and development phase, there are several barriers, particularly as they are not able to sustain multiple projects simultaneously and during the research process where not many resources are available, either technical or financial. Regarding the development process;

### **3. External development process**

They are seen as a barrier as there is not much control on the day to day processes, an issue which is repeatedly seen as a barrier by SMEs and brokers. On this, it has been stressed that due to the particularity of external projects, internal management cannot intervene and solve specific areas that might be better dealt with internally, or to have the control to direct specific approaches. Furthermore, issues with;

### **4. Legislation**

It is a perpetual issue in Biopharmaceutical projects, and even open innovation cannot be hindered by legal requirements and controls, as they are constant and rising.

### **5. IP issues**

Such issues arise when open collaborative projects produce some significant output which mainly happens due to the unclearness of who gets what, an issue which should have been identified and dealt with at the beginning of every open project. Regarding the

### **6. IP sharing**

It has been stressed repeatedly that the mind-sets and culture of the people that direct or have executive decisions (causal powers) over the design of the agreement can be a significant barrier when it is not done under open and clear deals or contracts.

Surprisingly, no barriers were identified during open collaborative projects with the government bodies and organisations, as large Biopharmaceutical firms have clear proof of concept of what the government requires at the beginning of the project. Usually, as the necessary and dependent relations between government agencies and large Biopharmaceutical firms and organisations are

clear, there is no condition under which issues might arise, as both sides have a clear and profound understanding of what needs to be done under open strategies and arrangements.

To evaluate the gains and the profits from open innovation projects, in terms of advantage creation for the organisation, the study assesses where and if such gains can be quantified. Evidently, the majority of the involved organisations have a positive attitude towards open innovation practices, as it is at some point profitable to their organisation (56%). At the same time, the remaining participants (44%) stressed the fact that in an industry where the process of research and development to market capitalisation takes from 12-15 years to occur, it is still too early to quantify any probable profits and revenues from the engagement with open practices.

The following section 8.1.3 summarises the conclusions of the analysis of the survey from senior managers of large Biopharmaceutical firms, who are among the pioneers of open innovation adoption in the sector.

### **8.1.3 Conclusions on the Large Biopharmaceutical Company Perspective**

The study identified the viewpoint of senior managers in large firms and organisations concerning the overall effect of open strategies, particularly at the firms' contextual level. It has been argued that:

*“Open innovation seems to work out in terms of out and in sourcing technologies, but to date is still too early to speak about any feasible benefits and profits” (LF-10).*

It has been acknowledged that as many industries and companies have been looking the open innovation concept in terms of research and development issues; large pharmaceutical firms are now engaging themselves with such strategic approaches.

Further, it is seen as an opportunity to create different business models by building on partnerships and collaborations which provides a positive aspect instead of competing and duplication which can lead to inefficient use of resources, *“but it will not be a panacea” (LF-01/12)*. It has also been identified

as a good way to find the best individuals to work on a problem, or a project. However it is quite challenging to find the right people and create the agreements which reward all the parties according to their individual needs. At this point, the *causal powers* of the collaborative individuals collaborating for the first time is likely to fail, as managing an open project is a skill in itself and it can be costly (*time and opportunity*) to learn.

Several aspects were identified as having a positive impact; product pipeline, and with an open mind-set; creativity; flexibility and speed can be achieved with minimum effect to the project budget. Furthermore, it increases the added value of completed projects which then maximises the IP, along with the research and development of the involved parties. At the same time, open innovation has been characterised as a paradox, as innovation by its definition implies openness to other ideas and to the outside so open innovation is a repetition of previous concepts. Nonetheless, it can and has effectively diversified a part of the operations, but needs more time to see actual results.

The vast majority of respondents considered open innovation as a future study because it was proven that it can create potential profits for organisations. Even though that might be the case with large bio-pharmaceutical firms, open innovation is not seen as a “panacea”; or a tool of many, that when used properly, can effectively create a positive variation for the organisations without excluding potential issues or barriers that can arise from its adoption.

Therefore, the open innovation approach will be moving, evolving and developing. Not only is it relatively new, but it has also been identified as having *“Implications to external ideas and outside source technologies that can maximise a firms' IP, and assist during the development process” (LF-04)*

The following chapter 9 consist of the study's discussion and conclusions which was driven through the research analysis in chapters 5, 6, 7 and 8. The conclusions comprise of the explanation of the strategies used by SMEs and large firms during their innovation process and progress, and how open innovation is perceived and used as a business model from firms and organisations in the Biopharmaceutical sector.

## 9. Conclusions, Contributions and Recommendations

The purpose of this chapter is to provide a succinct summary of the research regarding the outcome and overall contribution of this study. Furthermore, it provides recommendations for future work, including implications for research, and also provides a further clarification of open strategies for practitioners.

On the onset of the study three objectives were established as follows:

### 1) Open processes and relationships:

#### Process:

Explore the processes and relationships between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies

### 2) Operational Significance of Open Innovation Strategies:

#### Process:

Evaluate the significance of open innovation strategies in terms of its fundamental properties and aspects, such as in/out source, IP in/out source and open collaborations.

### 3) Critical Realist Perspective:

#### Process:

Explain in a critical lens the structure in which open innovation processes are exercised within the Biopharmaceutical sector.

This chapter discusses the key findings of the research objectives set out in Chapter 2. Section 9.1 delivers a summary of the research outcome, followed by section 9.2 which discusses in depth the main contribution of the study. Section 9.2.1 describe how open strategies are implemented by the firms

populating the Biopharmaceutical sector, in a multi-layered approach, which comprises of the firm level as well as the contextual level. Finally, section 9.3 depicts the overall contribution of the study in terms of policy implications, limitations of the approach and recommendations for future research.

## 9.1 Summary of the research outcomes

The research aim, objectives and questions presented in chapters 2 and chapter 3, denote open innovation as a novel business approach, which is gaining momentum in Biopharmaceutical firms and organisations.

**Objective 1: Explore the processes and relationships between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies**

For research objective 1, the study identified that innovation processes for SMEs is viewed as a collection of component models, such as:

- 1) The Business Innovation Model,
- 2) The Innovation Process Development Model,
- 3) The Open innovation Network Model, and
- 4) The Lead user Innovation Model.

Biopharmaceutical firms' main focus is on innovation and novel technologies. Through these processes they develop strong collaborative agreements with various individuals, firms, organisations and national and international bodies and associations (DiMasi et al, 2003, p. 152). For large firms and organisations, open innovation is now becoming a significant part of their progress as they actively and effectively diversify their internal activities to external associates (Laursen and Salter, 2005). It has been noted by the literature that open innovation is becoming a **“buzz word”** (Spithoven et al, 2012), which is supported by the study. An increasing number of companies' are now adopting open models and strategies, indicating a buzz around the open concept. To date there is no firm evidence supporting the argument that open innovation is a success story.

**Objective 2: Evaluate the significance of open innovation strategies in terms of its fundamental properties and aspects, such as in/out source, IP in/out source and open collaborations.**

The outcomes of objective 2 specified that the open concept is gaining some momentum in the industry, particularly with Biopharmaceutical firms and organisations (Munos, 2009). This only represents one element of their approach. Several SMEs, and the majority of large firms and organisations utilise in/out source techniques for their business process. Nevertheless their adoption varies, as not all the in-sourcing or out-sourcing activities are done under the open innovation umbrella. Further, in terms of value capture and creation, Biopharmaceutical firms do provide evidence of this, but due to the nature of their business this evidence is limited, as the production cycle of a new molecular entity takes from 12-15 years (DiMasi and Grabowski, 2007). It is too early to see the impact on profits, particularly when some companies have only just adopted such strategies.

**Objective 3: Explain in a critical lens the structure in which open innovation processes are exercised within the Biopharmaceutical sector.**

The outcomes of objective 3 detailed that a critical realist approach can explicitly describe how specific entities and individuals with their causal powers have a direct effect in designing and executing a business plan (Sayer, 1992). To this end, CEOs, directors and managers of SMEs and large firms who participated in the study have the power to adopt or exercise a particular business approach, either open or closed. Additionally, critical realism can identify why and how such activities and approaches occur, as it investigates the structural dynamics of the individual; this addresses the lack of ontological depth of positivism and constructivism. Key decisions in the industry are controlled by a small number of key individuals (Hara, 2003; Gassman et al, 2008), so the study supports the use of critical realism as a paradigm of choice as it delivers an explanatory approach. This approach has significant implications to social sciences as it is not solely associated to a single methodology, but can be seen as a channel towards broader access to mixed methods.

## 9.2 Theoretical contribution of the study

The study revealed an evolving tendency towards research and publications on open innovation, but the review of the literature (chapter 2) acknowledged a number of gaps concerning the existing knowledge of open innovation, particularly within the context of the Biopharmaceutical industry.

Most research to date on open innovation is influenced by positivist and constructivism paradigms (chapter 3), whereas methods and alternative paradigms such as critical realism are non-existent. This study offers a critical realist perspective of open innovation with the use of a triangulation of qualitative methods such as interviews (CEOs and managers of SMEs, knowledge brokers) and online surveys (CEOs and directors from large firms and organisations) through the data collection and investigation process (chapter 4). Consequently, the interpretation of critical realism which is integrated with empirical work delivers a fruitful contribution towards understanding the open paradigm in innovation research. In this regard, the critical realist approach revealed that decisions and approaches of a firm towards its strategic goals are shaped and constantly changing as a result of a newer better or faster approach.

To deliver a more profound understanding of the open concept, individuals in key positions have been investigated in terms of their underlying structures and several aspects of their involvement in relation to critical realism. Such elements include the causal powers of individuals that can lead to innovative business applications and their necessary and contingent relations which can lead to collaborative projects and arrangements.

The result as regards to the components of critical realism offers a deep understanding of the causal mechanisms (Bhaskar, 1978; Sayer, 1992). This makes critical realism a paradigm influencing the research in open innovation. With the use of retroductive reasoning, the study revealed how the CEOs and brokers, engage in open strategies, underlying and identifying that personal agendas, attitudes and culture are responsible for developing or adopting particular approaches.

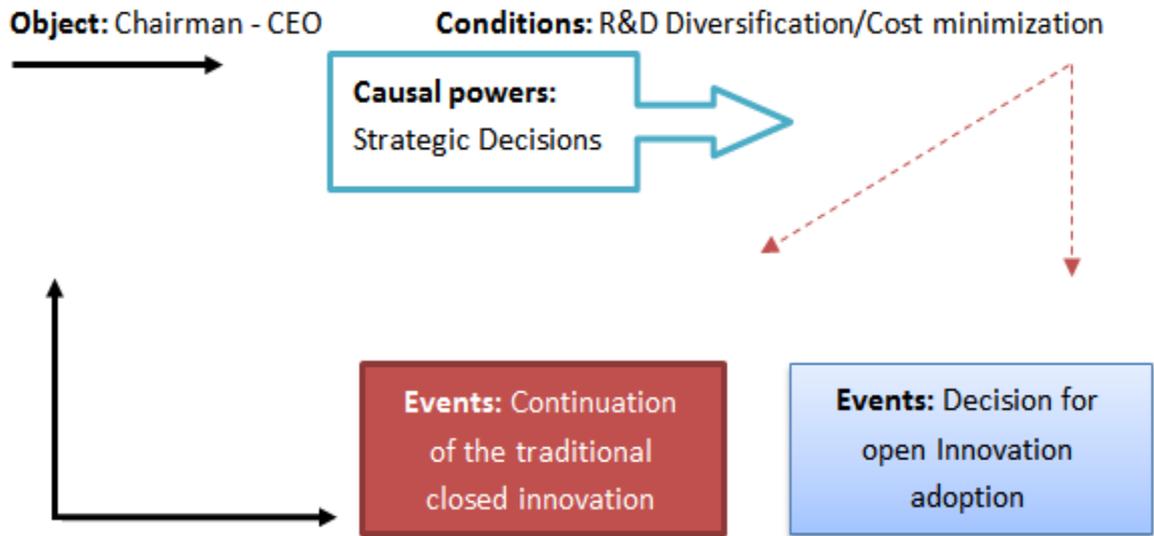
### 9.2.1 Critical Realism and Multi-layered factors influencing open innovation

To organise the conception of the research, the ontological and epistemological concerns can reveal the significant areas that influence the structure of the research (Sayer, 1992). Now as ontology delivers answers to questions of existence such as what is open innovation, by using critical realism under particular conditions, it can provide answers regarding the adoption of strategies by Biopharmaceutical firms, and their relation to open innovation.

In the critical realist lens, the study perceives open innovation as an interaction between actors - individuals, through the empirical observation of events that contribute to a larger incident. In principle, by stratifying that “*real*” entities with their “*causal powers*” can create “*actual*” approaches which can be “*empirically*” observed and experienced (Bhaskar, 1978, p. 13), the study utilises the approach that CEOs (*entities*) with their decisions (*causal powers*) can formulate specific approaches (*events*) that can be empirically observed. The factors influencing the adoption of open innovation are the *causal powers* of *objects* and *entities* that are consequential in equilibrium, such as their existence at the **micro-meso-macro** individual and firm level and in a contextual-industrial level.

Figure 65 illustrates the critical realist approach and factors that influence specific decisions towards the adoption of open innovation practices:

**Figure 65: The structure of causal explanation in critical realism**



**On-going development:** Events within a firm affect its progress and its strategy, as they are not static and can be amended over time.

Necessary relation



Conditional relation



Source: Sayer (1992, p. 109)

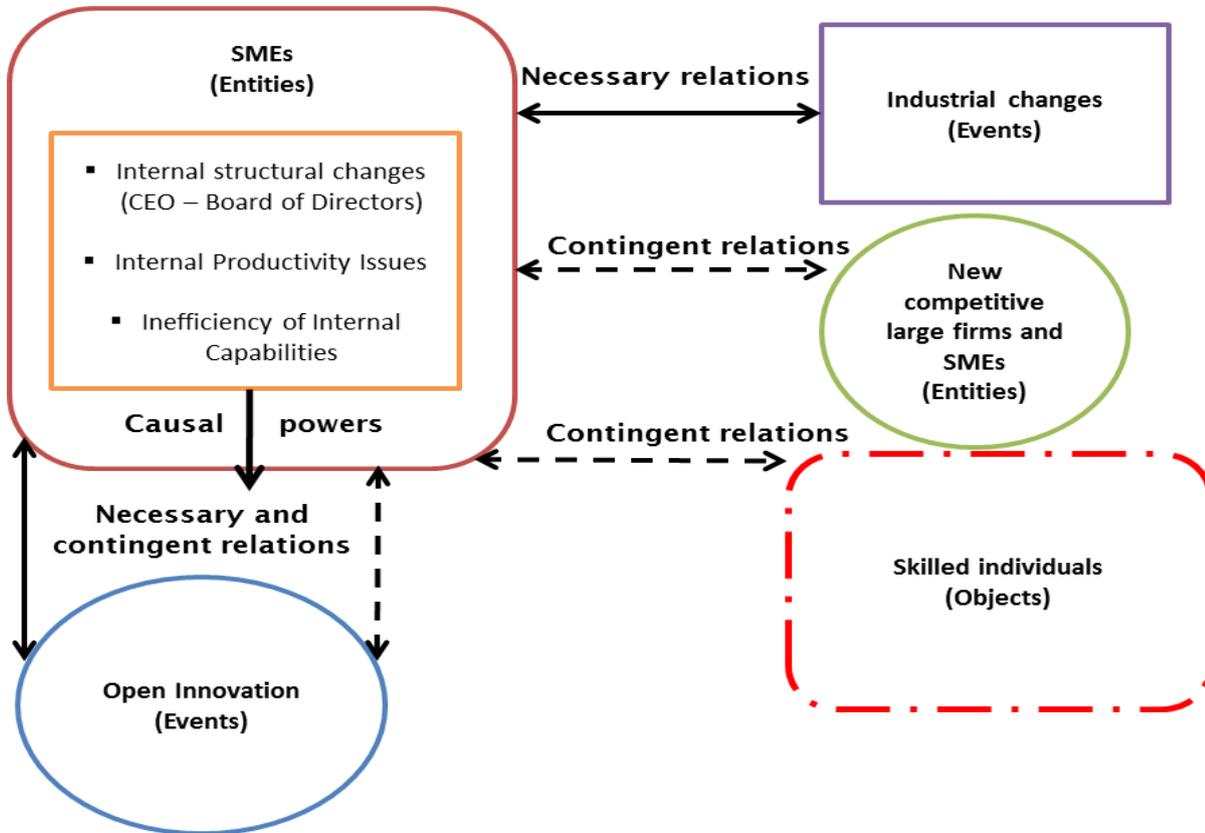
As social structures are characterised as ontological real entities (Bhaskar, 1978), firms that engage themselves in business activities through the interactions of individuals can be characterised as ontological real entities, as they have particular powers that create events under specific conditions. It has been argued that particular characteristics and leadership of top managers make a difference in strategy formulation and performance (Hambrick and Mason, 1984), and was pointed out that “*power may emanate from a manager’s personality*” (Finkelstein 1992, p. 510; Waldman et al, 2001). As the CEO is the person to whom all organisational employees are ultimately accountable (Daily et al, 2002, p. 391), the study captures, through semi-structured interviews, the approach of CEOs and senior directors in terms of the involvement of the firm they represent with open innovation.

The following sections 9.2.1.1, 9.2.1.2 and 9.2.1.3 provide a detailed view of the study’s approach towards open innovation approach from the perspective of SMEs, knowledge brokers and large Biopharmaceutical firms.

9.2.1.1 Structure of SMEs during the implementation of their strategy

Figure 66 illustrates the factors that influence the development of open innovation practices in SMEs based on a multi-layered approach.

Figure 66: Factors influencing open innovation in SMEs



In an intransitive domain, figure 66 illustrates the formation and the hierarchy of a social structure which has particular “positions” associated with certain roles. In this study, a social structure can be an *entity* (SMEs) that through its *particular structures* (general meetings - CEOs), has *causal powers (underlying authorities)* can create certain decisions (Sayer, 1992, p. 92). These strategic decisions are over and done with, through their *necessary and dependent relations* (internal and external factors), which when exercised deliver the on-going process of the current business model, or the adoption of a new and more open approach.

Evidently, the entities (SMEs) in which individuals (CEOs and directors - objects within entities) play a significant role can be traced on the micro-meso-macro framework, where the influences (causal power) of the specific

individuals affect innovation and the strategies firms adopt. From the multi-layered viewpoint, the study with the use of retroduction reasoning traces and identifies that the individuals (**CEOs**) and the mechanisms (**decisions**) they put in motion are responsible of producing and facilitating innovation and open strategies in the Biopharmaceutical sector. As it was indicated, knowledge brokers identify bio markets from the particular collaborations that are taken forward into development of diagnostic compound, as external cooperation is the key to our innovation process.

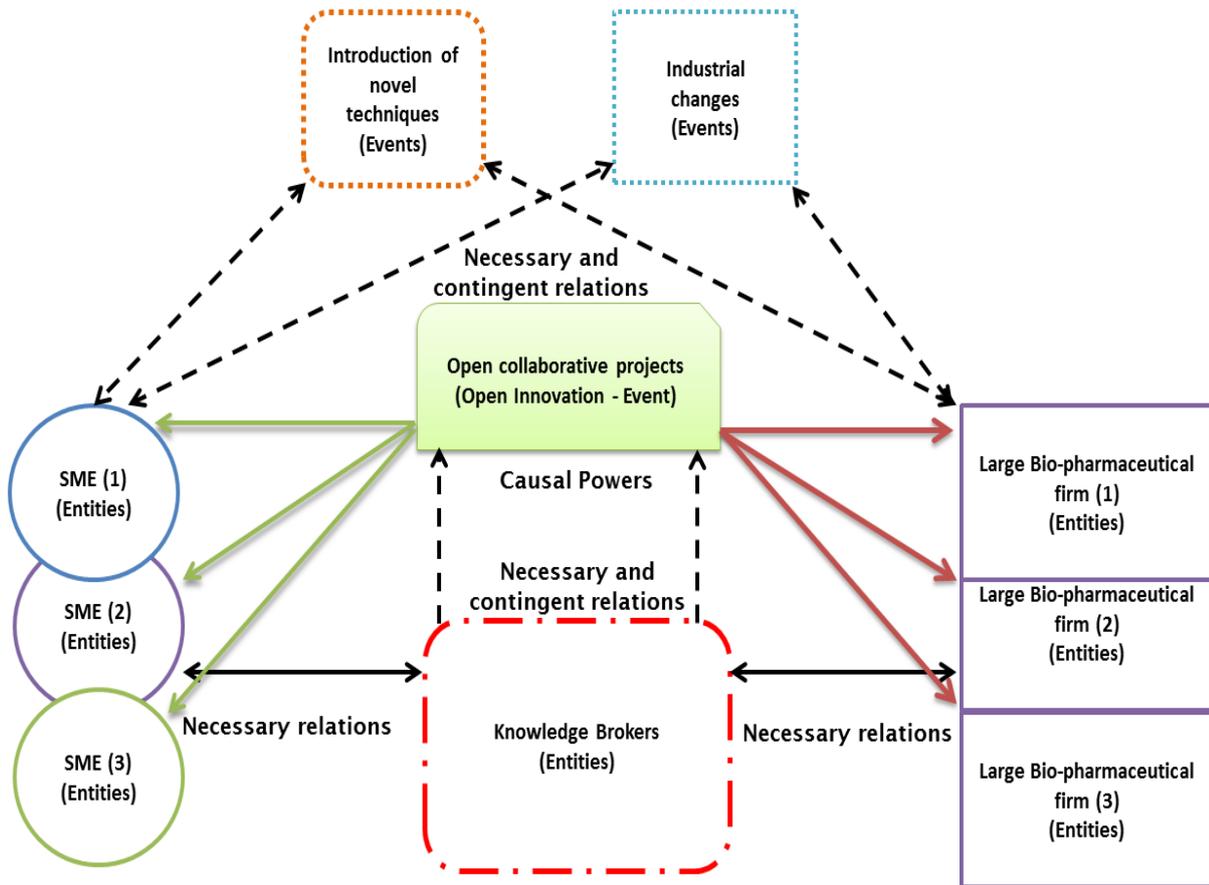
Clearly, entities (***general meetings***) and individuals (***CEOs -directors***) have a direct influence (***causal powers***) on the current business model (***mechanism***) of the firm, which lead to the continuation or to the adoption of a new business approach (***event***). Although these decisions are made on a micro firm related level, the application of the business model has a multi-layered effect, as it pre-arranges the relations of the firm with individuals both internally and externally. Moreover it clarifies the relations with various 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.

#### **9.2.1.2 Structure of Knowledge Brokers in the open innovation sphere**

Through figure 67, the study illustrates the factors that were identified to influence open innovation within the industry based on a multi-layered approach.

Brokers have provided strong evidence for open innovation operations across a multi-layered approach, as the interviews with brokers displayed the highest levels of knowledge regarding the open innovation approach. *By having the appropriate people (**entities**) driving it (**causal powers**), the open innovation approach can deliver significant changes (**mechanisms**) to the research and development processes of a firm* (KB – 1 to 8).

**Figure 67: Factors influencing the presence of Knowledge Brokers in open innovation**



Given the fact that the particular individuals are with their necessary and dependant relations closely linked with various firms and institutions, they can be accountable for aiding the adoption and facilitation of strategic decisions and implementations within the Biopharmaceutical sector. For this purpose, several brokers have indicated that sharing information and matching technologies is their primary job

The study contributes to support the use of a critical realism, as it can trace and identify how and why particular incidents occur given the fact that the individuals responsible for such incidents are identified and proven to be of imperative assistance to any organisation.

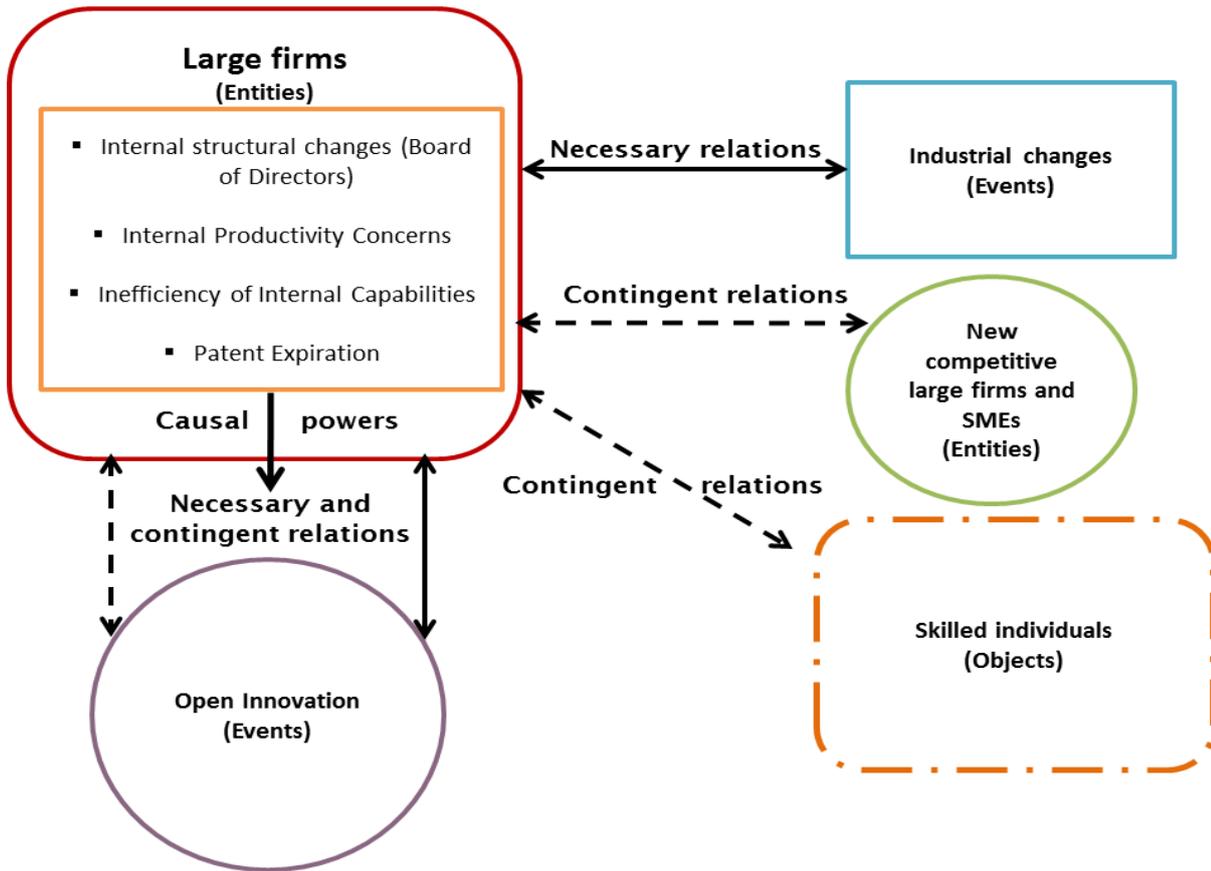
### 9.2.1.3 Structure of Large Biopharmaceutical firms during the implementation of their strategy

Similarly, for large firms and organisations, entities and objects (*board of directors* and *general meetings* and *CEOs*) have a direct influence (*causal powers*) on the current business model (*mechanism*) of the SMEs, which lead to the continuation or to the adoption of a new business approach (*event*). It was indicated that the decisions made on a firm related level had a multi-layered effect, as it influenced the organisations relations with individuals within the firm such as CEOs and externally with academics. These relations have to do with various firms and organisations, as well as with government agencies, both on a national and international level.

Given the fact that the particular individuals that are closely linked with the traditional ways and aspects of the traditional pharmaceutical model, they are directly accountable for the adoption and facilitation of strategic decisions and implementations. Several individual attitudes were indicated where managing an open project is a skill in itself and it can be costly (time and opportunity) to learn. The study contributes to the existing social debate and supports the use of a critical realist lens, as it can trace and identify how and why particular incidents occur given the fact that the individuals responsible for such incidents are identified and proven to be of imperative assistance to an organisation.

Figure 68 illustrates the factors that influence open innovation in large firms and organisations based on a multi-layered approach.

**Figure 68: Factors influencing open innovation in large firms and organisations**



It is widely acknowledged in the industry and the literature, that pharmaceutical companies need to adopt a more effective approach to their R&D operations, and open innovation has been confirmed to be a notion of substantial interest for the pharmaceutical industry that can have a positive impact on R&D productivity (Schuhmacher et al, 2013). Interestingly enough, as the industry has been characterised as a prisoner of its past successes (Gilbert et al, 2003, p. 73), it is extremely hard and difficult to change the culture that has been embedded in the particular industry for more than 100 years.

Noticeably, the industry had some examples where past success influenced discussions in the wrong direction, such as the merge of Human Genome Sciences by GSK, a merge very promising, but later on was seen that as the

culture in both companies was different, thus the project was condemned with failure<sup>21</sup>. Furthermore, on a similar note, Peter Ringrose a former CEO of BMS, argued in 1998 that the company on its current model could double the number of new drugs within the year 2000, thus doubling that new output in growth and achieve three product launches annually by 2003<sup>22</sup>, a promise that was not delivered, as the difficulties on a regulatory basis were increasing year by year. More specifically, table 22 below explicitly describes how critical realism can deliver answers to the research objectives and questions based on the multi-layered analytical approach.

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<sup>21</sup> Three Lessons From GlaxoSmithKline's Purchase Of Human Genome Sciences - <http://www.forbes.com/sites/matthewherper/2012/07/16/three-lessons-from-glaxosmithklines-purchase-of-human-genome-sciences/>

<sup>22</sup> BRISTOL-MYERS SQUIBB SEEKS TO DOUBLE NEW PRODUCT LAUNCHES, BMS OUTLINES AMBITIOUS R&D GOALS AT MEETING FOR WALL STREET ANALYSTS - <http://www.prnewswire.co.uk/news-releases/bristol-myers-squibb-seeks-to-double-new-product-launches-bms-outlines-ambitious-rd-goals-at-meeting-for-wall-street-analysts-156438075.html>

Table 22: Research objectives and questions

Open innovation in the Biotech and Pharmaceutical Industry	Outcome of Data collection	Methods	
<b>Objectives</b>	<b>Questions - Data Collection</b> “SMEs (Semi structured interviews) - Knowledge Brokers (Semi structured interviews) - Large firms and organisation (Online survey)”	<b>Critical Realist Interpretation in the Study</b>	<b>Level of Data Analysis</b>
<b>Objective 1:</b> Explore the processes and relationship of and between SMEs, large firms and organisations in the Biopharmaceutical sector in relation to open innovation strategies	<b>Question 1:</b> As innovation in the pharmaceutical industry is considered as a science process where findings are translated into clinical compounds that are subsequently marketed as drugs (Smits and Boom, 2008), firms use innovative methods, approaches and techniques in order to expand and enhance their capabilities. The study identifies 4 models, namely the business innovation model, the innovation process development model, the open innovation network model and the lead-user innovation model. At the heart of the specific models, innovation is identified	Events / Necessary and Dependent Relations (CEOs and Senior directors in SMEs through their network and capabilities create the necessary condition in which a firm can engage in innovative activities and events)	Micro-Meso-Macro - Firm level

<p>as the most significant aspect of their business approach, as it is considered as the Alpha and Omega, and the driving force of the existence of a firm.</p>		
<p><b>Question 2:</b> The study identifies that open innovation is adopted from a significant amount of SMEs (27%), with large companies simply follow the leader, in a form of strategic R&amp;D diversification, as the majority of large companies (83%) engage themselves in open strategies and activities. It has also been identified that although open innovation sounds like a new way forward, the mind-sets of CEOs and directors are not convinced as the traditional pharmaceutical model is embedded in their business culture. Even though it has been indicated that open innovation is now becoming a buzzword, its adoption by several large firms and government organisations suggest that there is a further element in openness rather than being a management fad.</p>	<p>Events (Collaborative efforts are seen as events which create open innovation practices)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>

<p><b>Question 3:</b> As large firms have been identified as the initial adopters of open innovation practices (Chesbrough, 2003a), the study through interviews with industrial experts identifies that several large firms like Lilly and Merck have a positive attitude towards openness and even though several large firms advertise that they are adopters, reality is rather different.</p>	<p>Events / Necessary and Dependent Relations (Large Biopharmaceutical firms are seen as the pioneers of open innovation “Lilly and Pfizer” by creating innovative ways of drawing in individuals and companies through various events such as the InnoCentive initiative by Lilly</p>	<p>Micro-Meso-Macro - Firm level</p>
<p><b>Question 4:</b> As with every strategy, open innovation is considered as a long-term approach as in big Pharma, as the process of R&amp;D takes from 12-15 year (DiMasi and Grabowski, 2007), thus any adoption or change of a business approach has to be done on the long-term.</p>	<p>Events / Necessary and Dependent Relations (open innovation strategies are formed by the management of large firms by effectively creating a network around their technologies that are outsourced for R&amp;D diversification and cuts, as the process of R&amp;D in the sector has several stages that require time and financial</p>	<p>Micro-Meso-Macro - Firm level</p>

		resources which can be found externally)	
<p><b>Objective 2:</b> Demonstrate the significance of open innovation strategies in terms of its fundamental properties and aspects, such as in/out source, IP in/out source and open collaborations.</p>	<p><b>Question 5:</b> It has been identified that the vast majority of SMEs (90%), engage themselves in collaborative agreements and partnerships in all three levels, such as with academics and PhD candidates in the micro, various other SMEs and large Biopharmaceuticals in the meso and with government organisations and EU bodies in the macro. Now, although collaborations exist in a large scale, only a quarter (27%) of SMEs is collaborating in under open innovation practices.</p>	<p>Necessary and Dependent Relations / Events (In terms of R&amp;D, open innovation creates the necessary events in which the firm through its network and capabilities can reach in a higher level of innovation)</p>	<p>Micro-Meso-Macro - Firm level</p>
	<p><b>Question 6:</b> Intellectual property is characterised as a “must have” element in any Biopharmaceutical firm, as it secures and protects their know-how and technological innovation. Taking into consideration that it secures their position, SMEs tightly protect their Intellectual Property and are reluctant in sharing or uncovering information easily, with an exception of the firms that adopt open innovation strategies.</p>	<p>Underlying Mechanisms / Causal Powers (IP itself is an asset which gives security and a sense of comfort to firms as it secures the technology and know-how. Within the open innovation context, IP can play an important role as it has the capabilities of bringing</p>	<p>Micro-Meso-Macro - Firm level</p>

	companies together by sharing or creating new IP)	
<p><b>Question 7:</b> It has been identified that boundaries regarding open innovation practices are concentrated around trust and day to day control. SMEs that are engaging themselves with open innovation practices do not face serious internal boundaries as they have a clear plan that doesn't create any internal conflict. Similarly, in large firms, day to day control of partners is a significant barrier during open strategies and internal capabilities are also an issue, particularly when a department is not capable to produce any output during open arrangements.</p>	<p>Underlying Mechanisms / Causal Powers (open innovation creates hurdles as when a development takes place outside the boundaries of the firm, it is unknown how it will be delivered)</p>	<p>Micro-Meso-Macro - Firm level</p>
<p><b>Question 8:</b> Brokers are seen as carriers of innovation from one side to another (SMEs and large firms). A significant proportion of SMEs (40%) are using brokers when internal capabilities are short. Regarding large firms, brokers play an important role (67%) as seekers of innovation, information, technology exchange and access to funds.</p>	<p>Necessary and Dependent Relations (Brokers have the necessary connections to create tensions between individuals, firms and government agencies, such as the Technology Strategy Board and the Medical Research</p>	<p>Micro-Meso-Macro - Related</p>

	Council)	
<p><b>Question 9:</b> A significant amount of SMEs (27%) adopt open innovation strategies as there is a strong protective attitude since the notion of sharing and working together is not a priority of CEOs as they have different mind-sets. As for large companies, although it is advertised that open innovations is a direction they follow, it is too early to speak about profits, but in terms of technological advantage, firms' such as Lilly shows evidence of such gains, then again, it is still early to talk about profits.</p>	<p>Underlying Mechanisms (open innovation has the means to enhance and expand productivity through connections for development with external resources)</p>	<p>Micro-Meso-Macro - Related</p>
<p><b>Question 10:</b> Framework 7 and the MRC technological collaboration are among the examples where open innovation is exercised with success. Although to date there is a limited number of successful examples in the pharmaceutical industry, there is a positive attitude from both SMEs and large firms.</p>	<p>Events (From the adoption of such strategies, we can empirically observe examples in a macro-meso-micro level, when collaborative events build from necessary relations had an impact either in research or development of pharmaceutical compounds)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>

<p><b>Objective 3:</b> Explain in a critical lens the structure in which open innovation processes are exercised within the Biopharmaceutical sector.</p>	<p><b>Question 11:</b> Various ways of interaction have been identified in all three levels, such as with academics and PhD candidates in the micro, other SMEs, large Biopharmaceuticals and contract research organisation in the meso and with government bodies such as the NHS and MHRA and EU funds and programmes in the macro. In doing so, firms have altered their attitude and became more subject to in-source information coming from outside, but at the same time the mind-sets of CEOs and senior directors are still a barrier during several cases in terms of in-sourcing and/or outsourcing. This happens due to the institutionalisation of their process with the traditional pharmaceutical model, which is opposite to the open innovation business model.</p>	<p>Causal Powers / Events / Necessary and Contingent Relations (Events are created from the causal powers of CEOs through collaborative relations with PhD candidates, firms and government organisations. SMEs and large Biopharmaceutical firms engage themselves in dependent collaborations in doing so)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>
	<p><b>Question 12:</b> In all cases, the attitude and mind-sets of CEOs and directors are responsible for the R&amp;D activities, whether under traditional closed or open innovation practices and are always exercised under tight control.</p>	<p>Mechanisms / Causal Powers (CEOs through their position make decisions that change or continue their R&amp;D projects)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>

	<p><b>Question 13:</b> Either on a firm or an industrial level, innovation plays a significant role, as without innovative methods and techniques, SMEs would not be able to secure any funding or support. This is observed by all SMEs that the creation of new compounds and molecules are associated with innovative methods and techniques. For large Biopharmaceutical firms, the case is similar, but rather than securing funds and resources, they are on the search for acquiring further and future revenues for their investors, with open innovation being a significant model towards this direction.</p>	<p>Mechanisms / Causal Powers (The necessity to attract investments and create a new “blockbuster” compound and the capabilities of CEOs and CSO in delivering a novelty)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>
	<p><b>Question 14:</b> Open innovation is seen by firms, particularly large Biopharmaceutical companies as a way of diversifying R&amp;D expenditure. At the same time, governments and EU organisations see it as a way of reducing costs and enhancing efficiency through collaborative efforts. All together, the decisions made by the EU and the UK government are influencing firms to engaging in open innovation</p>	<p>Underlying Mechanisms (open innovation promotes a way in which companies can work with each other and the industry can see breakthrough achievements through such approach)</p>	<p>Micro-Meso-Macro - Firm and Related level</p>

### 9.3 Contribution and Concluding remarks

The analysis provided new insight into the research objectives and questions, in terms of how they are embodied and answered through the process of the data collection, and their interpretation based on a critical realist perspective. As an emerging concept with actual and potential adoption in a variety of business sectors across the globe, the importance of the open innovation model is central to the academic as well as the political debate (Chiaroni et al. 2009). The literature (Chesbrough, 2003a; Chesbrough et al, 2006; Gassmann 2006; Vanhaverbeke and Cloudt 2006; West et al, 2006) suggests several research streams in which open innovation can be found, such as:

- 1) Globalisation of innovation
- 2) Outsourcing of R&D
- 3) Early supplier integration
- 4) User innovation
- 5) External commercialisation and application of technology

Consequently, the study evaluated the specific approaches from the standpoint of the UK Biopharmaceutical sector, which comprises of SMEs and large firms, and with knowledge brokers playing an important role between them. More specifically, as the research was separated into three parts, it supports that:

- I. **SMEs** exhibited significance reluctance in adopting new and promising business models, but nonetheless open approaches seems to be implemented in a small scale.
- 1) The literature stresses the significance of SMEs towards the open innovation concept (Bianchi et al, 2011; Huizingh, 2011; Keupp and Gassmann, 2009; Lee et al, 2010; Lichtenthaler and Ernst, 2009; Lim, 2008; Rahman and Ramos, 2010; Van de Vrande et al, 2009). This study indicated that one of the most significant factors towards the transition of a “closed” to an “open” strategy is the mind-set and mentality of senior executives. The majority of CEOs and directors participating in the study showed an institutionalised mind-set towards

what Hara (2003, p. 15) suggested “*a traditional linear pharmaceutical model, which provided innovation in the industry for almost a century*” as a significant model used by everyone in the sector. This linear model has been in existence for many decades thus the reluctance of executives, particularly in SMEs to change.

- 2) Even though there is a substantial adoption of open strategies (27%), in the majority, SMEs are mainly focused on a full-term commercialisation plan, an approach which was common with Biopharmaceutical firms and organisations (Bianchi et al, 2011; Hunter and Stephens, 2011; Sheridan, 2011). This was due to the uncertainty and lack of trust elements which have been pointed out in this study.
- 3) This study identified that in SMEs, CEOs and senior managers through their *causal powers* create particular *circumstances* under which a *business model occurs*. Strategic activities can be identified and categorised in terms of their value creation and capture. As several firms adopt such open approaches (Lee et al, 2010; van de Vrande et al, 2009), this study identified that it occurs when internal R&D are limited or when an opportunity occurs from the connections they develop within the sector.
- 4) The majority of SMEs have been identified as having strong collaborative ties with various key players which in the vast majority are other SMEs. This is not necessarily an indication that they are being used under open arrangements, as collaborations have been the norm in this sector for many decades (Powell et al. 1996; Teece, 1986). Senior executives of SMEs stressed that ideas existing outside their boundaries are of high significance, without necessarily taking place under open arrangements, but based on “*paid upon results*” agreement.
- 5) The use of critical realism assisted in clarifying that the *CEOs and senior managers* in SMEs are *responsible* for the *strategic approach* of the firm, and any alteration, adoption or continuation of a specific progress is *determined* and *controlled* by the *particular individuals* (Sayer, 1992). Through critical realism, the study identified and placed CEOs at the centre of the firm, as their decisions are necessary and essential for the continuation of the firms’ existence. In a stratified ontology, their

commands and connections create what is known as the empirical domain (ibid).

- II. **Knowledge brokers** observed that open innovation is becoming a more and more popular “buzzword” for the industry, but as yet has not become proven or dominant business logic.
  1. The literature stresses that brokers play a significant role in the open innovation process (Abbate and Coppolino, 2011; Gassmann et al, 2008). These are entities and individuals who have always been involved with such activities, thus their viewpoint matters significantly (Pawlowski and Robey, 2004). This study recommends and receives their perspective, as they have been suggested by several CEOs to play a significant role towards their innovative performance.
  2. Brokers indicated that CEOs have an insightful idea as to what their business strategies should be and through their actions and connections create different strategies. Noticeably, through critical realism the study identified that the *agenda* or *mind-set of individuals* such as CEOs and senior directors, have a profound *effect in adopting* open strategies, but has not yet become the dominant business logic.
  3. Nonetheless, some examples were identified where open activities could benefit the participating parties, such as the **EU Framework 7** or the **MRC** through government funding bodies such as the **BBSRC**, elements stressed by Sheridan (2011). More specifically, in a macro level, several national and international organisations have been identified to play a significant role in shaping and expanding the open concept.
  4. CEOs have been identified that through their *causal powers*, create *mechanisms* which in several cases are protective of their in-house capabilities, consequently creating a false impression when open arrangements are discussed.
- III. **Large Biopharmaceutical firms** still tend to follow the leader when particular strategic changes occur in the industry.

1. As Eli Lilly started its open projects, several large firms and organisations followed, particularly Pfizer who utilised in-licensed techniques for a drug called Lipitor (Gassman et al, 2010). As early adopters of the open strategy, these firms have led the way and several other firms now follow.
2. Through their *causal powers*, the senior managers and CEOs (*individuals*) in large Biopharmaceutical firms create *mechanisms* that support the use of open arrangements, such as the in-source and out-source of specific technologies.
3. Evidently, there is a strong association of large firms and organisations with open strategies supporting the argument that open innovation is now considered as one viable strategy by large Biopharmaceutical firms. More and more, open innovation is now adopted, not only because of its novel nature, but also because many firms do not want to be in the loop when some breakthrough idea or technology is developed through such strategies.
4. The majority of respondents stressed that open innovation is now considered as a strategic process for large Biopharmaceuticals, but thus far, no feasible profits have been identified. As the product development cycle in the industry takes from 12 to 15 years and cost millions if not billions to be developed (DiMasi et al, 1991, 2003; DiMasi and Grabowski, 2007), the firms in this sector have to date not seen any viable profits.
5. Despite this, large Biopharmaceutical firms and organisations identify SMEs as one of the main sources of collaborative engagement (Forrest and Martin, 1992), particularly under the open umbrella. Nonetheless, SMEs indicated exactly the opposite as in the majority they work or collaborate with other SMEs. This supports the argument that if open innovation is successfully implemented in large firms, then SMEs would be more actively involved in the same process.

All in all, although open innovation has been highlighted as a new way forward for the industry, the extent and proven benefits of its adoption have been limited. As the production of an NME consist of a long process which can take

up to 15 years (DiMasi and Grabowski, 2007), it is difficult to identify successful examples for both SMEs and large organisations. Additionally, it was evidently clear in both SMEs and large firms that the concept is not fully understood, thus creating a false impression, especially in the case of large Biopharmaceuticals. As the brokers indicated, there is a different approach or agenda when SMEs and large firms engage in open strategies, and more importantly, not going with an open hand but with the notion “*what is in it for me*” (KB-08).

Consequently, what has been identified is that open innovation is a business model that is adopted by the industry but to date not the dominant one; there is a variation of models Biopharmaceuticals use during the process of their strategy. The study also recognised the importance of internal competences such as internal R&D capabilities and management, which are critical factors in ensuring the success of projects, both internally and externally, either in the form of openness or closed approach. Open innovation can be a method or a model that can assist firms in their value creation and capture, but is not the only alternative.

In terms of the theoretical practicalities of the study, a critical realist approach can be utilised as an explanatory tool in identifying an underlying objective. In addition, due to its ontological and epistemological commitments, critical realism has significant implications to social scientists. Critical realism gives explanations about a phenomenon not solely with the use of a single methodology, but also with the use of various and triangulated methods.

### 9.3.1 Implications for Policy

The analytical objective of the study, which included all three levels, identified a number of policy conclusions, as the assumptions of the study emphasise and reinforce how important collaboration is within the industry (Academics – PhD candidates, SMEs, Large Biopharmaceuticals, universities, national and international bodies and associations). In doing so, SMEs and large companies follow a particular collaborative approach when they need to improve the research and development process of their NMEs. Furthermore, the study identifies that open innovation and closed innovation, is not the main models

used by SMEs, but there is a variation on the approaches that are currently utilised.

The development of a framework that consists of the three multi-layered levels gave a detailed view of the process firms adopt when embracing open innovation approaches. Analytically, the micro level is identified to consist of the relations and engagements of a firm with internal and external individuals that assist in the creation and distribution of innovation. The meso level comprises with the relations the firm develops with other firms, research organisations, institutions and venture capitalists, particularly for technological advance and funding opportunities. Finally, the macro level consists of the relations and links a firm creates with various governmental bodies and organisations on a national as well as international level, in a form of obligatory contracts, particularly for regulatory authorities as well as contractual obligations from governmental agreements, particularly from the UK government and the EU. This distinguishes that there is a link between the overall impact of open strategies from not only the perception of the firm, but also the various actors that engage in the process.

In a macro level, government bodies and organisations have a positive effect on both SMEs and large firms, as they promotes collaboration, sharing and working together on a common goal, aspects that were not used before in the industry, or only used on a few occasions. It is pertinent that government policies continue with the promotion of such projects, not only as a tool of open expansion but also as a way of securing that new and innovative ideas can come to life faster and better not from single entities, but within a consortium. As the study identified the importance of the government in shaping and developing projects that can increase innovative participants, it should be considered as an on-going process and treated with high importance, not only for open innovation purposes, but also for the expansion of Biopharmaceutical innovation.

The results of the study further suggest that the application of open strategies, insofar as reflected by the tight control of patents especially in SMEs, are strong evidence that open innovation strategy is not considered equally important by all types of firm. In the case of large Biopharmaceutical firms, as

the pressure from the board of directors to produce faster and better results is building up, the majority of large companies are adopting such approaches, as diversified positions as important for the accomplishment of new methods, techniques and the production. For example, large firms and organisations were historically working with various academics on a *micro* level and with several academic institutions and universities on the *meso* level, as they are the main source of early and pre-competitive technologies and inputs.

As the study emphasises the potential benefits and obstacles of open innovation, it seems that there is the need to develop an effective and efficient technique or approach by which firms can identify whether such strategies can effectively and efficiently lead to their technological and technical expansion. As the study indicated, open innovation is growing into a business approach, if not yet as a dominant strategy with major commercial impact in the sector, but certainly more than a fad. To date, not many studies have successfully identified a method from which accurate outcomes from open strategies can be measured, thus it is essential and necessary and imperative to develop such effective tools.

### 9.3.1.1 Limitations of the Study

The findings of the study provide useful insights and accelerated the understanding of open innovation from a multi-level focus, but there are some limitations. To begin with, as the study emphasised on the adoption and utilisation of open innovation in the Biopharmaceutical industry, it can be argued that due to the morphology of the sector, several firms might be prone to changes. This occurs as the particular firms and organisations are constantly researching novel technologies that push towards an open direction, rather than being driven by introduction of a new management concept or theory.

As the study uses critical realism as an analytical paradigm, it covers a single point of time, and it cannot account for the influence of the evolution of the firms and the managerial wisdom of senior managers in SMEs and large Biopharmaceutical firms. There are some aspects that were not included in the study, such as the point of the NME process for every firm and organisation,

which emerged from the interviews, as well as the survey, and identified the innovation depth of the specific firms, either SMEs or large Biopharmaceuticals.

Since the study emphasised the use of qualitative tools, there is the need to introduce effective analytical implementations to measure the adoption of open strategies by Biopharmaceutical firms, by evaluating the efficiency of their R&D diversification, if any. By doing so, it will deliver a better understanding of whether the sector is actually moving towards the open concept and simultaneously, if open innovation assisted in value creation, capture and expansion based on specific quantifiable measurements.

### 9.3.1.2 Further and Future Research

Based on the limitations of the study, several suggestions for future research have arisen.

- As the study uses critical realism as a paradigm, it can only take a snapshot in time and describe what happens at a specific moment in time.
- 1. There is the necessity to re-visit the objectives at a specific point in the future in order to develop a longitudinal study. This will not only support the initial finding, but also give further details as to the future of open innovation in the sector.
- 2. Provide a clear insight as to whether open innovation assisted in the creation and capture of value in an industry defined by long product development cycles. As the study focused on the adoption and exercise of open innovation in the Biopharmaceutical sector, there is a necessity to examine its presence in different sectors, such as manufacturing automotive and others.
- 3. A case study is necessary to evaluate the precise level of adoption, engagement and profits or revenues from such strategies. Due to its characteristics a case study can provide a holistic or an embedded view concerning the topic in question, in order to explore the causality and underlying principles of open innovation (Yin, 2003).

- A case study can explore the causation of openness and find underlying principles that helped to produce and facilitate such open approaches (ibid).
- 1. There is a variation of models utilised by SMEs, and to date, no study has examined the space between closed and open innovation, but only observed if open innovation is been used or not.
- 2. With the use of a multiple case study approach, the exact processes can be identified and clarified, elements which are not thus far been systematically examined by the literature.
- 3. Through a careful consideration of the specific dimensions of the Biopharmaceutical sector, a case study can create a holistic and embedded comparison (ibid); to show the similarities and differences of firms within different subsectors of the same industry, such as biotech and medical devices.
- The study identified a variety of strategic approaches, when firms' progress their innovation plans, rather than open and closed.
- 1. It is necessary to explore and examine the specific strategies, which can be described as: closed innovation, focused innovation, merges and acquisitions and open innovation.
- 2. This occurs as the study identified a strong influence, existence and interaction in the levels between closed and open, making it vital for further investigation.
- 3. This approach will clarify further the various levels and procedures in which open innovation strategies operate.

By combining a firm and a contextual level of analysis, the study provides a better understanding concerning the magnitude to which open innovation is seen as a strategic approach. Open innovation is regarded as an opportunity to create different approaches and models during a firm's innovation process (Chesbrough, 2003a). This occurs by building on partnership and collaboration, providing a positive characteristic which can lead to the expansion and efficient use of resources.

Although recent studies have investigated the concept in various industries and contexts (Du et al, 2014; Felin and Zenger, 2014; Gambardella and Panico, 2014), the management processes which are vital towards the performance of open projects have not been studied yet. Nonetheless, open innovation must be realised as just a tool of many rather than a panacea. What can be perceived as a further step is the clarification of whether the open innovation concept is actually profitable, not only within the context of this study but also for all other economic sectors.

The literature supports the use of external knowledge assets to successful innovative activities in various sector (Belderbos et al, 2014; Christensen et al, 2005; Chesbrough and Crowther, 2006; Chesbrough et al, 2006; Gassman et al, 2010). Thus it is imperative to evaluate such actions across the UK sector. By doing so, a study will be able to identify whether the concept can be applied to a variation of sectors and industries, or it has specific applications which are only exercised under particular assumptions. This will indicate whether the concept can be solid and applicable to other sectors and industries, or has specific effects under particular assumptions and should be treated as a momentarily “*rush*”.

# Appendices

## Appendix 1

### Letter of request:

Dear Dr,

I am a PhD student at Southampton University, School of Management, my supervisors are Dr Lorraine Warren, Director of the Centre for Strategic Innovation ([www.soton.ac.uk/csi](http://www.soton.ac.uk/csi)) and Dr Stephen Rhys Thomas, who is Co-founder of the Centre and a seasoned Pharmaceutical Industry executive, now spearheading the University's research into current patterns of innovation and technology translation in the pharmaceutical industry. My project concerns the improvement of innovation processes in SMEs as well as large pharmaceutical companies, which will be classified through the internet, for their innovating ability and geographic location (UK based). Throughout a close study, to identify the relationship that exists between the SMEs and large firms in product, service and process development.

I am particularly interested in your views as regards your firm's innovation processes (which may include R&D, IP and co-development). The purpose of writing to you is to request if you could possibly provide me with an interview (questions in file attached, approximately 30 minutes). Alternatively, if there is someone better placed in the company to discuss these issues, it would be most helpful if you could make the contact for me, and I will approach them directly. I can reassure you that all participants are guaranteed complete confidentiality.

As academics, of course we attempt to publish the outcomes of our research, but our papers are focused on generalised management processes within the pharmaceutical sector, not the specifics of development projects. Additionally, the findings will be available to you to review, as the research emphasis the significance your firm provides to the process of the study of innovation, or if you wish to keep anonymity that is completely respectable.

Thank you for taking the time to consider my request. Please contact me by phone at 07858179380 or by e-mail at [sm8v07@soton.ac.uk](mailto:sm8v07@soton.ac.uk).

Yours sincerely,

Stefanos Marangos

**SMEs semi-structured interview questions:**

Question 1: Can you please tell me what kind of innovation process your firm has?

Question 2: Do you develop the technology by yourselves or is there any co-development with other firms or institutions?

Question 3: Are you prone to any outside source technology?

Question 4: Are there any particular pathways when you try to out-source technology?

Question 5: Are the company's R&D been covered by its technology or do you in-source or out-source technology?

Question 6: Do you think that Agents or Brokers assist the company in any way?

Question 7: What role does the company's intellectual property play in the process?

Question 8: How do you manage your IP?

Question 9: Do you encounter any problems when doing your innovation process?

Question 10: Do your process as a long term strategy, is it likely to change?

Question 11: Do consider that open innovation is a strategy option?

## Appendix 2

### Letter of request:

Dear,

My name is Stefanos Marangos and I am a PhD student at Southampton University, School of Management, my supervisors are Dr Lorraine Warren and Dr Stephen Rhys Thomas. The project concerns the improvement of innovation processes in SMEs as well as large pharmaceutical companies, and aims to identify the relationship that exists between the SMEs and large firms in product, service and process development, within the open innovation context.

I am particularly interested in your views as a knowledge broker (intermediaries that increase the number of external exchanges by stimulating innovation) with regards to the interactions of SMEs and large firms, in terms of Co-development, R&D and IP. The purpose of writing to you is to request if you could possibly provide me with a face to face interview (questions in file attached, approximately one hour). The focus of the interview will be based on your experience and views working with SMEs and large bio-pharmaceutical companies, regarding their management processes during the implementation of their strategy.

Additionally, the findings will be available to you to review, as the research emphasis the significance of knowledge brokers in the study of innovation, or if you wish to keep anonymity that is completely respectable.

Thank you for taking the time to consider my request. Please contact me by phone at 07858179380 or by e-mail at [sm8v07@soton.ac.uk](mailto:sm8v07@soton.ac.uk) to arrange a meeting whenever is convenient by you.

Yours sincerely,

Stefanos Marangos

**Knowledge Brokers semi-structured interview questions:**

Question 1: What is your view of the extent of Open Innovation adoption in the Biopharmaceutical Industry?

Question 2: In an Open Innovation paradigm, where R&D diversification and collaborations play an important role towards the technological and financial expansion of a company, how important do you consider the effect of such approach?

Question 3: Are there examples of any major gains from such involvement for the stakeholders (individuals-academics, firms and various organisations “Angel funds”)?

Question 4: Knowledge brokers or agents appear to play an important role in innovation and technological transformation at a public, firm and industrial level. Are there any intermediate functions between SME’s - knowledge brokers - large companies?

Question 5: Do you consider that a company’s intellectual property assist in the expansion of Open Innovation practices in any way? If so how is that applicable to the organisation?

Question 6: SMEs often allow patent agents the responsibility of their patent portfolio; but do patent agents or brokers work with large companies in matching technologies and create collaborations between the two? If so, how is that applicable and how successful it is?

Question 7: Can you identify the main difficulties working with Academic partners, firms and trade or government organisations under “open” arrangements?

Question 8: What role do trade organisations (BIA, ABPI) have in this space? Are there any potential conflicts of interests, and if so, how this effects your presence in the context and why?

Question 9: In your experience with open innovation activities, what are the main barriers the firm face during the application of such strategies?

Question 10: Do you consider open innovation processes to be a beneficial long term approach for large companies or SMEs in the Biopharmaceutical Industry? If so, why? If not, why?

## Appendix 3

### Letter of request:

Dear Dr,

We are conducting a study to measure the effectiveness of Open Innovation in large and SMEs Biopharmaceutical firms, and we have selected you to participate in this research. My name is Stefanos Marangos and I am a PhD student at Southampton University, School of Management, my supervisors are Dr Lorraine Warren, Director of the Centre for Strategic Innovation ([www.soton.ac.uk/csi](http://www.soton.ac.uk/csi)) and Dr Stephen Rhys Thomas, who is Co-founder of the Centre and a seasoned Pharmaceutical Industry executive, now spearheading the University's research into current patterns of innovation and technology translation in the pharmaceutical industry. The project concerns the improvement of innovation processes in large Biopharmaceutical companies as well as SMEs, for their innovating ability and geographic location (UK based). Throughout a close study, to identify the relationship that exists between the large firms and SMEs in product, service and process development.

We are particularly interested in your views as regards to innovation processes (which may include R&D, IP and co-development). The purpose of writing to you is to request if you could possibly participate in an online research (<https://www.isurvey.soton.ac.uk/6401>), which evaluates open innovation in the Biopharmaceutical sector from the view of the large Biopharmaceutical companies. I can reassure you that all participants are guaranteed complete confidentiality.

We plan to conduct the study by the end of April 2013, and we would really appreciate your participation (approximate duration 15 minutes). As academics, of course we attempt to publish the outcomes of our research, but our papers are focused on generalised management processes within the pharmaceutical sector, not the specifics of development projects. Additionally, the findings will be available to you to review, as the research emphasis the significance large Biopharmaceutical firms' provide to the process of the study of innovation, or if you wish to keep anonymity that is completely respectable.

Please feel free to contact me by phone at 07858179380 or by e-mail at sm8v07@soton.ac.uk for any enquiries you might have.

Thank you for your participation.

Yours sincerely,

Stefanos Marangos

**Survey questions for large Biopharmaceutical firms:**

Biopharmaceutical Innovation - Opportunities and Barriers

The Biopharmaceutical industry plays an important role to in innovation as there is much more benefit to working together on innovative projects rather than isolated. The purpose of this research is to identify prospects and obstacles to open innovation (e.g. co-development with other companies and institutions), explore these barriers and suggest whereas open innovation activities are exercised in the industry.

The survey will take you 5 to 10 minutes of your time.

Thank you for your participation.

**Section 1: Details**

Question 1.1

Name: (optional)

---

Question 1.2

Email Address: (optional)

---

Question 1.3

What is the name of your organisation? (Optional)

---

Question 1.4

Size of the organisation:

● 1-49

---

● 50-249

---

● 250+

---

### Question 1.5

What is your current job title?

---

## Section 2: Innovation Strategy

### Question 2.1

Strategy is the approach towards value creation and business development, overall how satisfied is the organisation with the result of the development of the innovation business strategy? Please select a point on the scale if it applies to your organisation

Deeply dissatisfied

Highly satisfied

1

2

3

4

5

6

7

8

9

282

10

## Question 2.2

During the assignment of a project what is the level of satisfaction with each of the following areas?

Identification of relevant partners	<input type="radio"/>				
Contractual negotiations	<input type="radio"/>				
Project management/administration	<input type="radio"/>				
Communication within the strategy team	<input type="radio"/>				
Time management	<input type="radio"/>				
Technical capabilities of the selected team	<input type="radio"/>				
Cost	<input type="radio"/>				
IP management	<input type="radio"/>				

## Question 2.3

During the progress of the action strategy, did the organisation create any networks?

- Yes
- No

## Question 2.3b

With which of the following groups does the organisation actively collaborate in its innovation networks? (Select all that apply to your organisation)

283

Large Biopharmaceuticals

---

SMEs

---

Competitors

---

Universities

---

Customers

---

Government - local regional or national

---

Venture Capital

---

Other

---

#### Question 2.3c

What is the impact of the networks for the organisation?

Positive

---

Neither Positive or Negative

---

Negative

---

Unknown

---

#### Question 2.3d

What are these interactions about?

Funding opportunities

---

Collaborations

---

IP improvement

---

R&D efficiency

---

R&D diversification

---

Other

---

Question 2.4

Did the organisation encounter any “gatekeepers” during its action strategy?  
(Gatekeepers are individuals who control access to offers or to key decision researchers)

Yes

---

No

---

Question 2.4b

What were these interactions with “gatekeepers” about?

Access to contracts

---

Access to technologies

---

Access to funds

---

Access to skilled individuals

---

Other

---

Question 2.5

During the application of the development strategy did the organisation encounter any setbacks or barriers?

Yes

No

---

Question 2.5b

If yes, can you please identify which barriers you encountered?

Research process

---

Development process

---

Legislation issues

---

Partners

---

IP management

---

Other

---

### Section 3: Open Innovation

Question 3.1

Have you heard the term Open Innovation?

Yes

No

---

Question 3.1 b

In your knowledge, which of the following is the best description of Open Innovation?

- It's about obtaining new people in the company to act as consultants to help with a specific problem we can't solve by ourselves.

---

- It's the collaborative effort with a number of individuals outside the organisation to work on a project for mutual gains.

---

- It's a way of carrying out innovation activities without the need for an internal R&D department.

---

- For out-licensing and in-licensing of intellectual property

---

- I am uncertain what Open Innovation is

---

Question 3.2

One definition of Open Innovation is the use of purposive inflows and outflows of knowledge to accelerate innovation. Have you ever engaged or will engage in an Open Innovation project?

Yes

---

No

---

Question 3.2b

If Not then why?

Did not accept the term

---

Previous experience did not live up to expectations

---

Did not have an opportunity yet

---

● Other

---

Question 3.2c

Which models of Open Innovation have you applied or will apply? (Select all that apply to your organisation)

Acquisition

---

Strategic alliance

---

Open source

---

Licensing (in-out)

---

Collaboration and co-development

---

Consultancy

---

Don't know

---

Other

---

Question 3.2d

In the case where the organisation adopts Open Innovation, why did the organisation decide to engage with an Open Innovation model? (Select all that apply to your organisation)

Did not have the capacity to carry out the work

---

Considering that outsourcing of expertise would save funds

---

The need to bring new ideas into the project to benefit from a different

approach

- To convert a member of a group to obtain suitable position for funding

---

- Believe in a multidisciplinary approach that can produce a successful productivity

---

- To create revenue by acting as an intermediate to support and facilitate Open Innovation

---

- To enable utilisation of any IP produced into other non-competing markets

---

- Identified that it was the only likelihood of commercialising the firm's ideas

---

- Required someone else's IP

---

- Cost saving

---

- Reputation of partners

---

- Other

Question 3.2e

Before the organisation made the decision to engage with Open Innovation, what were the greatest concerns or reservations? Please select the relevant level of concern for each of the issues listed

IP issues	● ● ● ● ●
Costs	● ● ● ● ●

Ability to find the right people to be involved

---

Potential cultural differences between your organisation and those you wished to engage with

---

Time constraints

---

Project management/administration challenges

---

Question 3.2f

During the progress of the Open Innovation strategy, did the organisation create any networks?

Yes

No

---

Question 3.2g

During the application of Open Innovation strategy did the organisation encounter any setbacks or barriers?

Yes

No

---

Question 3.2h

Did Open Innovation create any advantages for the organisation?

Yes

Too early to say

---

- No

---

Question 3.3

Does the organisation consider Open Innovation as a strategy in the future?

- Yes

- No

---

Question 3.4

Please give your opinion about the effect of open innovation. (optional)

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We would like to thank you for your time and participation for this survey

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