

**Academia - Industry Collaboration in
Translational Medicine**

**Thesis submitted in partial fulfilment of the requirements for the degree
of Doctor of Philosophy**



Natasha L. Davie

Nuffield Division of Clinical Laboratory Sciences

and

Wadham College

University of Oxford

Supervisors: Prof. Deborah R. Gill and Prof. Richard Barker

Trinity Term 2016

Academia - Industry Collaboration in Translational Medicine

Natasha L. Davie

Nuffield Division of Clinical Laboratory Sciences and Wadham College,
University of Oxford

Thesis submitted for the degree of Doctor of Philosophy, Trinity Term, 2016

Abstract

Collaboration between academia and industry has been the focus of numerous government reports and initiatives over the past 15 years, and is increasingly recognized as an effective way to capitalize on the UK's world-class research base. However, there is a need to further understand the role of such collaborations in the field of translational medicine, where the path to market is particularly lengthy, expensive, and risky, due to complexities associated with the clinical trial process.

This research uses a mixed methods approach to investigate collaboration in translational medicine at the University of Oxford. The project comprises three principal stages. First, a broad understanding of the current landscape of academia-industry collaboration in translational medicine was obtained by administering a questionnaire to academics who had received industry funding. Next, a deeper understanding of the barriers to collaboration was sought through semi-structured interviews with 27 academics. Finally, potential strategies to reduce practical barriers to the collaboration process were investigated through interviews with members of three groups within the university who interact directly with industry: Research Services, Oxford University Innovation, and Business Development.

This research constitutes the first empirical study on university-industry collaboration in translational research in the United Kingdom. It contributes to existing theory through the development of a new theoretical framework for the evaluation of barriers in terms of a) the practicalities of the collaboration process, b) the institutional environment and c) presiding cultures. Through these analyses, differences in experiences of barriers to collaboration emerged for clinical and non-clinical researchers. Furthermore, industry was seen as playing a crucial role in the translation of new therapeutics, especially in the funding of research that was perceived as being 'too risky' for Research Councils. Thus, reducing barriers to university-industry collaboration was seen as important to the realisation of public benefit from university research. Barriers were seen as being overcome, or avoided, via the formation of relationships between academics and companies at several different levels; while systems exist within the university to facilitate this, awareness and uptake of these systems was poor amongst the study population. Finally, if universities are to deliver impact as a key metric of performance, incentives within the university need to reward academics for commercialisation activities, in addition to publication. Through the suggestion of long and short-term strategies and a detailed analysis of industrial collaboration in this setting, this research has implications for both university and government policy.

Acknowledgements

The completion of a thesis is a catharsis that encourages reflection upon the many contributors to its development. First, I must thank Professor Richard Barker, for seeing the potential of this thesis before even I had, and for giving me the opportunity to realise it. Next, I express my deepest gratitude to Professor Deborah Gill, whose relentless support and encouragement provided the foundation for both academic and personal growth far beyond what I could have expected from four years in Oxford. I must also thank my funders, The SENS Foundation and the Radcliffe Department of Medicine.

To Professor Steve Hyde and the rest of the Gene Medicine group: Dr Lee Davies, Dr Ian Pringle, Dr Stephanie Sumner-Jones, Dr Rebekka Harding-Smith, Dr Cathy Oliveira, Dr Kristy Pluchino, Jack Tan, Agata Antepowicz, Joost Van Haasteren, Mary Connolly, Laura Moyce, Karen Bamford, Charlotte Rush and Tina Garland; thank you for welcoming me into your wonderful group, feeding me cake, and allowing me to infiltrate lab data days with snippets of qualitative research. A special mention must go to the soon-to-be Dr Jean-Francois Gelinas, for helping me find this home, and making it such a fun place to be. To my lovely friends at CASMI: Dr Suzanne Ii, Dr Liz Morrell, Stuart Faulkner, Emily Algar and Sam Bannon – thank you for the laughs, support, and for all the coffee breaks. An extra big thank you to Megan Morys-Carter whose friendship and encouragement have been so important throughout this process.

As an engineer trying to learn the ropes of the social sciences, I was very fortunate to have a lot of help from some remarkable academics. In particular, Professor Louise Fitzgerald, who is both an inspiration and a (very patient) friend, and Dr Pavel Ovseiko, who provided me with the tools to begin this project. In addition, I am overwhelmingly grateful to all of the academics and research staff who generously gave up their time and energy to participate in this study. It would not have happened were it not for you.

Throughout the highs and lows of research, the most stabilising force one can have are good friends, and in that sense I am truly blessed. Adie, Charlotte, Clare, Deni, Eleri, Kirsten, Megan, Tim, all you Wadham Women Weightlifters, and every person in Keble and Wadham Colleges, thank you, thank you, thank you.

Finally, I cannot even begin to express the gratitude I feel towards my family for their constant and unyielding support. Dad, for never faltering in your belief in me for a second. To my gorgeous, glorious Ben and Toby, you light up my life in ways I could never have imagined. James and Caroline, thank you, for bringing me home wherever I may be. And last, but never least, to my brave, incredible, inspirational Mum. Thank you, for the lessons on compassion and for your visits to Oxford when I needed them most. Your limitless love gave me strength and carried me through. This thesis is for you.

Declaration

This thesis has been composed by myself and has not been used in any previous application for a degree. There results presented herein were obtained by myself, except where acknowledged in the text. All sources of published or unpublished information have been specifically acknowledged by means of a reference or personal communication notation, respectively.

Table of Contents

Abstract.....	1
List of Abbreviations	9
List of Figures.....	10
List of Tables.....	11
Chapter 1: Introduction.....	12
1.1 Research Background.....	12
1.1.1 Translational medicine	12
1.1.2 Translation Gap 1: The ‘Valley of Death’	12
1.1.3 Academia-Industry Collaboration.....	15
1.2 Literature review of academia – industry collaboration.....	19
1.2.1 Method.....	19
1.2.1.1 Defining search terms	19
1.2.1.2 Reviewing the literature.....	25
1.2.2 Results	25
1.2.2.1 Collaboration Trends.....	26
1.2.2.2 Types of university-industry interactions	35
1.2.2.3 Positive aspects of collaboration	41
1.2.2.3.1 Academia	41
1.2.2.3.2 Industry.....	45
1.2.2.4 Negative aspects of collaboration.....	48
1.2.3 Summary.....	53
1.2.3.1 Identification of areas for further research.....	54
1.3 Theoretical frameworks.....	57
1.4 Research Questions.....	60
1.5 Outline of Chapters.....	61
Chapter 2: Methodology.....	63
2.1 Introduction and Research Design	63
2.2 Methodology and Philosophical Approach.....	66
2.2.1 Research Setting	67
2.2.2 Research Participants.....	69
2.3 Methods.....	70
2.3.1 Survey of Principal Investigators at the University of Oxford.....	70
2.3.1.1 Study population	71
2.3.1.2 Questionnaire development and administration.....	74
2.3.1.3 Questionnaire structure	75
2.3.1.4 Analysis	79
2.3.2 Interviews of Principal Investigators at the University of Oxford.....	80
2.3.2.1 Topic guide development and pilots	80
2.3.2.2 Participant recruitment and semi-structured interviews.....	82
2.3.2.3 Analysis	83
2.3.2.4 Reporting of results.....	85
2.3.3 Interviews with facilitating groups at the University of Oxford.....	86
2.3.3.1 Semi-structured Interviews.....	86
2.4 Ethical Considerations	87
2.4.1 Informed consent of participants	88
2.4.2 Confidentiality	88
Chapter 3: Survey of Principal Investigators at the University of Oxford.....	90
3.1 Introduction	90
3.2 Results	92
3.2.1 Data Collection and Analysis	92

3.2.2 Demographics.....	92
3.2.3 Motivations.....	96
3.2.4 Types of collaboration with industry.....	102
3.2.5 Phases of translational research.....	110
3.2.6 Advantages of Industry Funding.....	113
3.2.7 Disadvantages of Industry Funding.....	119
3.2.8 Barriers to Collaboration.....	131
3.2.9 Strategies to Improve Collaboration.....	132
3.3 Discussion.....	137
3.3.5 Summary and next steps.....	148
Chapter 4: Interviews with Principal Investigators at the University of Oxford	150
4.1 Introduction	150
4.1.1. Overview of interview process.....	151
4.2 Results	154
4.2.1 Data collection and analysis	154
4.2.2 The role of industrial collaboration in academic research	157
4.2.2.1 Non-clinical researchers	161
4.2.2.2 Clinical researchers.....	163
4.2.3 Barriers to academia-industry collaboration.....	164
4.2.4 Analysis of barriers	177
4.2.4.1.1 Academic vs industry cultures of ‘data-sharing’	181
4.2.4.1.2 Academic vs industry cultures of ‘time’	181
4.2.4.1.3 Academic vs industry cultures of ‘money’	183
4.2.4.1.4 Clinical vs non-clinical sub-cultures.....	185
4.2.4.1.5 Institutional factors.....	189
4.2.5 Strategies to improve collaboration.....	189
4.2.5.1 To encourage and attract new researchers to engage with industry	191
4.2.5.2 To help connect an academic researcher with the right company and individual for their needs	191
4.2.5.3 To provide guidance on how to engage with industry and what to expect during collaboration	193
4.2.5.4 To streamline the contracting process.....	193
4.2.5.5 Improve management of IP to maintain patents for longer	194
4.3 Discussion	195
4.3.1 Summary and next steps.....	198
Chapter 5: Interactions with facilitating groups at the University of Oxford	200
5.1 Introduction	200
5.1.1 University structure.....	202
5.1.2 Facilitating groups.....	204
5.1.2.1 Research services.....	204
5.1.2.2 Oxford University Innovation	205
5.1.2.3 Business Development.....	205
5.2 Results	206
5.2.1 Data collection and analysis	206
5.2.2 Process Overviews.....	207
5.2.2.1 The Contracting Process.....	209
5.2.2.1.1 Limiting steps – Review and Data Gathering.....	209
5.2.2.1.2 Limiting steps – ‘Marking-up’ and Negotiation ‘sticking-points’	210
5.2.2.2 Patenting and Licensing	215
5.2.2.2.1 Limiting steps – finding partners.....	215
5.2.2.2.1 Limiting steps – academic interference in negotiations	217
5.2.2.3 Business Development: Forming relationships.....	219
5.2.2.3.1 Limiting steps – Finding academic partners	220
5.2.3 Contributing factors.....	221

5.2.3.1 Poor knowledge transfer within the university	221
5.2.3.2 Difficulties in working with industry	226
5.2.3.3 Limited resources within facilitating groups	230
5.2.4 Strategies	231
5.2.4.1 Encourage and attract new researchers to engage with industry	233
5.2.5.2 Raise awareness of Business Development	233
5.2.4.3 Raise awareness of how to best engage with Research Services	234
5.2.4.4 Champion the creation and use of pre-negotiated contracts that have had input from multiple companies.....	236
5.2.4.5. Increase the patent budget for Oxford University Innovation <i>OR</i> Change incentive system for academics so they can patent later.....	237
5.3 Discussion	239
5.3.1 Summary	241
Chapter 6: Discussion and Implications	242
6.1 Introduction	242
6.2 Key Findings and Response to Research Questions	244
6.2.1 Research Question 1: What is the current landscape of academia-industry collaboration in translational medicine at the University of Oxford?	244
6.2.2 Research Question 2: What are the key barriers to collaboration in translational medicine, and to what extent do they impact the progress of collaborations?	245
6.2.3 Research Question 3: What managerial and/or organisational strategies could be implemented to maximise industry-academia research collaboration?.....	247
6.3 Contributions.....	248
6.3.1 Empirical contributions.....	248
6.3.2 Theoretical contributions.....	249
6.4 Limitations and future research	251
6.4.1 Internal validity	251
6.4.2 External Validity.....	257
6.5 Implications.....	258
6.6 Conclusion.....	262
References.....	266
Appendices.....	277
i. Confirmation of ethics approval for study.....	277
ii. Questionnaire for PIs conducting translational medical research.....	278
iii. Participant information sheet.....	284
iv. Interview topic guide for principal investigators	285
v. Information sheets on barriers and strategies provided to interviewees	286
vi. Anonymised List of PIs interviewed.....	288
vii. Interview topic guide for Research Services	289
viii. Interview topic guide for Oxford University Innovation.....	290
ix. Interview topic guide for Business Development.....	291
x. Anonymised List of members of RS, OUI, and BD interviewed.....	292

List of Abbreviations

ABPI: Association of the British Pharmaceutical Industry
BD: Business Development

CDA: Confidential Disclosure Agreement

CTRG: Clinical Trials and Research Governance

CUREC: Central University Research Ethics Committee

FEC: Full Economic Cost

GDP: Gross Domestic Profit

HEFCE: Higher Education Funding Council for England

HEI: Higher Education Institution

HESA: Higher Education Statistics Agency

IPO: Intellectual Property Office

MPLS: Mathematical, Physical and Life Sciences Division

MSD: Medical Sciences Division

MTA: Material Transfer Agreement

NDA: Non-Disclosure Agreement

OUI: Oxford University Innovation

PI: Principal Investigator

R&D: Research and Development

RS: Research Services

TCC: The Charities Commission

TTO: Technology Transfer Office

UAS: University Administration and Services

NOTE: FEC used interchangeably with overheads. PI used interchangeably with academic.

List of Figures

Figure 1.1 Overview of the translational process in healthcare research.....	18
Figure 1.2 Basic structure of theoretical framework.....	59
Figure 1.3 Overview of thesis structure.....	62
Figure 2.1 UK Higher Education Institutions (HEIs) research income from industry in medical sciences.....	68
Figure 3.1 Derivation of completed responses from the initial list of PIs obtained from Research Services.....	94
Figure 3.2 Frequency of motivations mentioned by respondents.....	103
Figure 3.3 Analysis of responses mentioning 'funding' as a motivation according to phrasing.....	104
Figure 3.4 Types of academia-industry collaboration for which academics have received funding.....	108
Figure 3.5 The number of different types of industry funding received by individual PIs.....	109
Figure 3.6 Phases of translational development	111
Figure 3.7 Overview of types of academia-industry collaboration.....	114
Figure 3.8 Number of PIs receiving 100% of their industry funding for research in a single development phase.....	115
Figure 3.9 Frequency of advantages/disadvantages of industrial collaboration by all respondents.....	130
Figure 3.10 Percentage of respondents responding either 'agree' or 'strongly agree' to pre-identified barriers to collaboration.....	133
Figure 4.1 Derivation of final interviewees from initial list of PIs obtained from Research Services.....	155
Figure 4.2 Key cultural and institutional factors.....	179
Figure 4.3 Schematic showing how different industry aims for clinical and non-clinical collaborations may contribute to different perceptions within these sub-cultures.....	188
Figure 5.1 Overview of university structure and interactions with external organisations.....	203
Figure 5.2 Overview of the contracting process for two-party agreements.....	214
Figure 5.3 Overview of Patenting Process and cumulative costs.....	218

List of Tables

Table 1.1 List of synonyms to inform search terms for Search 1.....	21
Table 1.2 List of search terms identified from three key publications for Search 2.....	23
Table 1.3 Search 3 search terms and results.....	24
Table 1.4 Features of academics and companies that participate in collaboration.....	34
Table 1.5 Different typologies used to categorise relationships between academia and industry.....	37
Table 1.6 Positive aspects of collaboration in academia.....	44
Table 1.7 Positive aspects of collaboration for industry.....	47
Table 1.8 Barriers to academia-industry collaboration.....	51
Table 1.9 Comparison of Academic and Industrial Research and Development.....	52
Table 1.10 'Common ground' between academia and industry.....	52
Table 2.1 Inclusion/exclusion criteria for Survey of Principal Investigators at the University of Oxford.....	73
Table 2.2 (a) Types and (b) stages of translational research.....	77
Table 3.1: Demographics for study population and survey respondents.....	95
Table 3.2 Overview of themes identified in responses to the open-ended question 'What was your main motivation for entering into collaboration with industry?'.....	97
Table 3.3 Types of collaboration used in survey and features.....	107
Table 3.4 Overview of themes identified from responses to advantages.....	120
Table 3.5 Overview of themes identified from responses to disadvantages.....	127
Table 3.6 Overview of strategies identified from survey.....	135
Table 3.7 Comparison of themes identified in disadvantages and barriers.....	141
Table 3.8 Comparison of themes identified in motivations and advantages.....	144
Table 3.10 Comparison of barriers and strategies to improve collaboration and whether their impact would be on a practical, institutional or cultural level.....	147
Table 4.1 Example questions from semi-structured interviews.....	153
Table 4.2 Demographics of study population, interview respondents and interview participants.....	156
Table 4.3 Overview of the role of industrial collaboration for clinical and non-clinical research.....	158
Table 4.4 List of assets both academia and industry bring to collaborations with the goal of translation.....	160
Table 4.5 Original barriers and refined barriers to collaboration.....	165
Table 4.6 List of barriers and suggested contributing cultural or structural factors.....	180
Table 4.7 Original and Refined Strategies.....	190
Table 5.1 Relating academic perceptions of facilitating groups with their constraints.....	208
Table 5.2 Limiting steps and overview of contributing factors.....	222
Table 5.3 Overview of Lambert Agreements.....	228
Table 5.4 Updated strategic aims from Chapter 4.....	232
Table 5.5 Author evaluation of strategies to improve collaboration.....	240

Chapter 1: Introduction

1.1 Research Background

1.1.1 Translational medicine

Translational research is a growing field that bridges the concepts of ‘basic’ and ‘applied’ research within a multitude of subjects, and has attracted interest among policy makers and academics in recent years. Within translational research, translational *medicine* is the ‘interface between basic science and clinical medicine’ (Woolf, 2008), with the aim of developing the discoveries made through academic research and applying them for patient benefit – bringing innovations from laboratory “bench-to-bedside”. To do this, an innovation must go through the process of ‘translation’ from pre-clinical testing to clinical application. Within the process of translation, as outlined in Figure 1.1, two translational ‘bottlenecks’ or ‘gaps’ have been identified. The first of these, T1, occurs due to the complexities of translating pre-clinical research into clinical research, and is colloquially referred to as the ‘valley of death’ due to the high attrition rates of the transition (Butler, 2008). The second of these, T2, sometimes referred to as the ‘adoption gap’, reflects the difficulties of translating new research findings, especially in public health, into everyday practice (Woolf, 2008).

1.1.2 Translation Gap 1: The ‘Valley of Death’

A 2016 report by the Tufts Centre for Drug Development estimated that the cost of developing a single prescription drug through to approval is \$2.5 billion, over \$1 billion of which constitutes the pre-clinical development costs of drug candidates that are ultimately unsuccessful (DiMasi et al., 2016). This represents a 145% increase over 2003 estimates of drug development costs, a

substantial rate of increase over a 13-year period (DiMasi et al., 2003). Furthermore, the 2016 study also estimated the average time to approval from the commencement of clinical trials to be in excess of 8 years, with an overall probability of approval of 11.83% (DiMasi et al., 2016). When including pre-clinical research stages, time to approval increases from 8 to 13 years on average, while the probability of approval decreases further (Dickson and Gagnon, 2004).

This increase in the cost, time, and attrition rate of drug development are commonly attributed to the increased levels of regulation observed over the past 20 years (Sood et al., 2009), arising in response to events such as the high profile safety-failures of drugs post-approval; for example, Vioxx in the USA (Horton, 2004). These increased regulatory requirements can be seen in the new mandates to include women and children in testing, as well as increased concerns about toxicity, potency, and patient monitoring (FDA, 2012, Behrman Sherman et al., 2011). Furthermore, in order to meet regulatory standards for demonstrating safety and efficacy, more research subjects are required, with clinical trial-samples increasing by an average of 7.47% every single year from the 1970s to 2001 (DiMasi et al., 2003). Finally, there have been substantial increases in the complexity of procedures performed on patients and the level of record-keeping required.

Thus the bar to regulatory approval is substantial, and not something that many academics are able to overcome: while 24% of drugs are identified in academia, almost none are maintained under academic control until approval (Kneller, 2010).

A study by Patridge et al. (Patridge et al., 2015) found that of 801 drugs that had originated in academia (identified via publication), 21 had academic sponsors listed on the Investigational New Drug (IND) application, the first stage of clinical research. Only 7 of these sponsors were listed as key players by the end of phase II, and only one academic institution, the US army, was granted approval for a new molecular entity at the end of clinical development.

The overwhelming majority of drug approvals therefore, are sponsored by small companies or big pharma (Kinch et al., 2014). However, in light of these trends, several studies are pessimistic

about the sustainability of this drug development process (Munos, 2009), as pharmaceutical companies are investing ever greater resources into Research and Development (R&D) for a constant output in terms of number of drug approvals (Scannell et al., 2012, Kaitin, 2010). Of those that have been approved, the majority are 'me-too' or addition-to-class drugs, i.e. analogues or modifications rather than innovative or first-in-class drugs (Lanthier et al., 2013). This is in contrast to drugs developed in academia, where 69% were classed as 'scientifically novel' (Kneller, 2010).

Furthermore, as 'blockbuster' drugs approach the end of their patent life, some companies are facing a 'patent cliff', with several drugs coming off patent, indicating a sharp drop in revenue (Kakkar, 2015), causing companies to cut costs by reducing in-house R&D spending (Raghavendra et al., 2012). Thus, it seems that the UK is operating a 'translational ecosystem' that is ultimately unsustainable (Pincus, 2009, Smith et al., 2011).

This 'valley of death' is also seen to contribute to the 'innovation gap' – the disparity between the high quality of UK research and institutions and the 'mediocre' resulting economic growth and development (Livesay et al., 2006). The UK is consistently ranked as the number one contributor to global progress in Science and Technology (Anholt, 2015), and in 2016 was designated as hosting 34 of the top 200 universities in the world (Education, 2016). Yet despite this stellar research base, the UK lags behind several competitors including France, Germany and the USA on most conventional measures of innovation, including R&D spending per GDP per capita and number of patent filings (OECD, 2015). A 2014 report by the Department for Business Innovation and Skills describes "average to low levels of new to market innovations," despite the strength of the UK's research base (Allas, 2014). This topic has been the focus of much government interest, and one commonly discussed strategy to bridge these gaps is to improve collaboration between Academia and Industry.

1.1.3 Academia-Industry Collaboration

The promise of collaboration to bridge the ‘valley of death’ was highlighted in Richard Lambert’s review into Business-University Collaboration, which found “clear evidence of the benefits which [collaboration] has brought both to the university system and to British business” (Lambert, 2003a). Since the publication of Lambert’s report in 2003, this area has been the focus of numerous other groups and government departments, with over 14 reports directly highlighting the importance of university-industry collaboration as a key factor in driving UK growth (CH, 2012, Docherty et al., 2014, Dowling, 2015, Hauser, 2010, Hauser, 2014, House of Commons, 2014, House of Commons, 2013, IPO, 2013, Lambert, 2003b, NCUB, 2012, NOCRI, 2015, Turville, 2007, Wilson, 2012, Witty, 2013, Young, 2013). The most recent of these, The Dowling Review of Business-University Research Collaborations, suggests the reasons for this interest are due to “the significance of research and innovation as drivers of a knowledge-based economy, coupled with longstanding concerns regarding the UK’s ... performance in converting research excellence into commercial success, and the need to boost UK productivity” (Dowling, 2015).

Indeed, when reviewing the most innovative or ‘transformational’ drugs developed over the past 25 years, one research group found that only four of the 19 drugs identified were completely researched and developed by one sector, identifying a complementarity between the role of the public sector in basic science, and the private sector in drug development phases (Chakravarthy et al., 2016). However, while it appears that there has been substantial investigation into the topic of collaboration as a means of improving innovation and growth (Stewart et al., 1999, Mueller, 2006), there has been much less research into the role of academia-industry collaboration in translational medicine. Furthermore, studies have shown that sector-specific dynamics play a significant role in shaping university-industry relations (Rappert et al., 1999). Thus, while the university-industry interface might be a key factor in promoting innovation (Mansfield, 1998), the complex and varied nature of that interface has not yet been explored and understood. It is a reasonable premise then, that as the ‘valley of death’ and other area-specific factors (e.g. the

requirement of substantial development costs and high levels of risk and uncertainty (Grabowski, 2006)) contribute unique characteristics to research in translational medicine (Pincus, 2009), they might also result in different pressures around academia-industry collaboration in this field. Thus, this research aims to identify, explore and understand these pressures in relation to existing knowledge on academia-industry collaboration. In pursuit of this, a review of the literature on collaboration between academia and industry in translational medicine was undertaken.

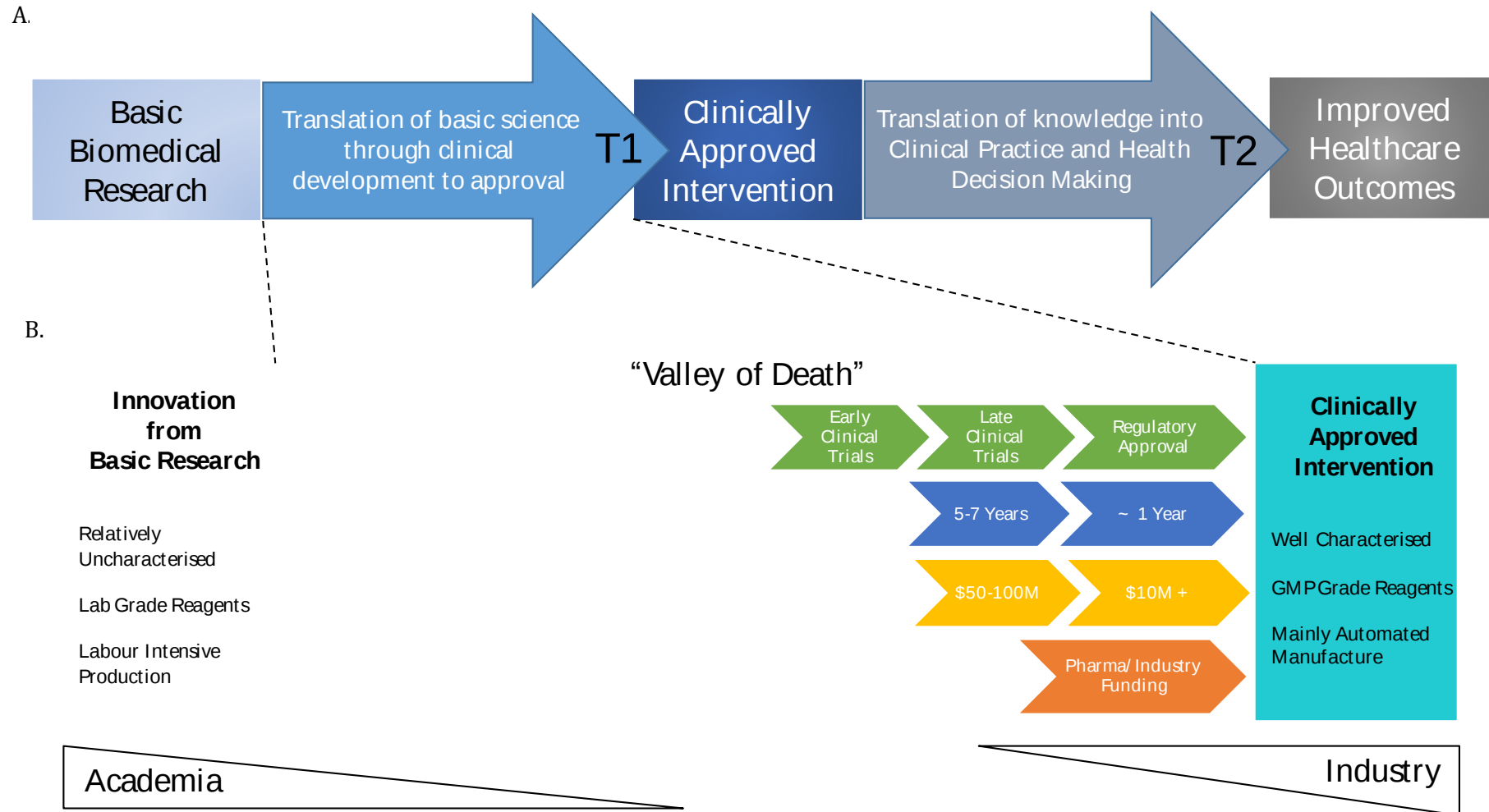


Figure 1.1 Overview of the translational process in healthcare research. (A) Translational process from basic research to patient outcomes. T1 indicates the first translational gap between pre-clinical research and regulatory approval; T2 indicates the second translational gap between regulatory approval and technology uptake and adoption. Figure (A) adapted from (Sung et al., 2003) (B) Further detail of translation gap T1 from basic research to clinical approval. The figure breaks the gap down into four aspects; the green row represents the stages of clinical development, the blue row is the approximate time taken per step, the yellow row is the approximate cost of completing each step and the orange row represents typical funding sources. The depth of shading indicates progression towards an approved product. The pink triangles at the bottom indicate the extent of involvement of both academia and industry. Figure author's own using information from (DiMasi et al., 2016, Dowling, 2015, Kaitin, 2010, Scannell et al., 2012)

1.2 Literature review of academia – industry collaboration

In this section, the published literature on collaboration between academia and industry is reviewed to explore the following questions: How do academia and industry currently interact in translational medicine? What forms do these collaborations take and what are the positive and negative factors affecting academia-industry collaboration? Where there is limited information specific to translational medicine, literature from other fields, particularly engineering and the physical sciences, is reviewed. From this literature, the primary models of interaction are summarised, as well as the predominant incentives, features, benefits and barriers.

1.2.1 Method

A scoping review was undertaken to explore the current literature and determine areas of future research. Daudt et al. define the aims of a scoping review as ‘to map the literature on a particular topic or research area and provide an opportunity to identify key concepts; gaps in the research; and types and sources of evidence to inform practice, policymaking, and research’ (Daudt et al., 2013).

This type of review was selected in order to allow for literature which comes from a diverse range of sources (including literature from economics, organisational studies, healthcare research, management, and medical journals), and to provide a broad level of comprehension as quickly as possible (Pham et al., 2014).

1.2.1.1 Defining search terms

A list of synonyms for the words ‘academia’, ‘industry’, and ‘collaboration’ was developed using literature and thesauri as a basis for search terms, which comprised Search 1 (Jesson et al., 2011).

This created the list of terms as shown in Table 1.1. This information was then used to search databases in combination (i.e. any term in academia AND any term in industry AND any term in collaboration) using Boolean search terms to account for differences in word format. Databases searched were PubMed, Web of Science and JSTOR, to account for the diverse fields in which research on collaboration is published. However, this search term strategy proved relatively ineffective, returning only 35 results from PubMed and missing many key texts, thus showing a very low recall. Additionally, several thousand results were identified using JSTOR and Web of Science which, upon review, were mainly not relevant to the search, showing a low precision (Table 1.1.), indicating that a different approach was required.

The Pearl Harvesting Information Retrieval Framework is a technique that is used to identify relevant publications (Sandieson and L., 2010) and was chosen instead of alternative techniques such as ‘snowballing’ to minimise bias. It involves the identification of keywords from existing important publications, either as specified by the author in the publication, or as identified from the bibliographic information such as the title, abstract and descriptors. For this scoping review keywords were identified from three articles (Mittleman et al., 2013) (Perkmann et al., 2013b) (Amabile et al., 2001a) for Search 2. These articles were chosen as they were published in a range of journals from different fields, had a high level of citation and spanned a large time period, to account for changes in the terminology used within a field as words evolve and acquire new meanings (Jesson et al., 2011).

Table 1.1 List of synonyms to inform search terms for Search 1.

Key Word and Synonyms	Academia	Academics, Academic institution, Scientists, University, Researchers, Research institution, Public, Publicly funded
	Industry	Pharma, Pharmaceutical company, Drug manufacturer, Drug company, Companies, Corporate, SME, Pharmaceutical industry, Biotech, Biotech industry, Industry, Company, Private, Privately funded
	Collaboration	Partnership, Alliance, Strategic alliance, Public-private partnership, Consortia, Pre-competitive consortia, Cooperative network, Relations, Relationship, Synergies, Open innovation, Technology Transfer, Entrepreneurship, Engagement, Collaborative research, Collaborative approach, Interaction, Interface
Search Term	((((((((((((Academi*) OR Academi* institut*) OR Academi* scientist*) OR Academi* research*) OR Scientist*) OR Research*) OR Research* institut*) OR Public) OR Public* fund*) OR Public* sponsor*)) AND (((((((((((((((Industr*) OR Pharma*) OR Pharma* compan*) OR Pharma industr*) OR Drug manufactur*) OR Drug compan*) OR Compan*) OR SME*) OR (Small and medium sized enterprise*)) OR Enterprise*) OR Biotech*) OR Biotech* compan*) OR Biotech* industr*) OR Private) OR Private* fund*) OR Private* sponsor*)) AND (((((((((((((((collaborat*) OR alliance*) OR strategic alliance*) OR public-private partner*) OR consorti*) OR pre-competitive consorti*) OR cooperative network*) OR relations*) OR synerg*) OR open innovation) OR technolog* transfer) OR entrepreneur*) OR engag*) OR collaborat* research*) OR collaborat* approach*) OR interact*) OR interfac*)) AND English[Language]	
# Results*	35 (PubMed), 8230 (JSTOR), 101,962 (Web of Science)	

Search 2 (search terms are shown in Table 1.2), returned 754 results from PubMed, and several thousand once more from JSTOR and Web of Science. Based on this, and while reviewing the results, it was decided that only PubMed results would be considered further, as these were more relevant to collaboration in the life sciences and translational medicine. Thus 754 papers were retrieved based on the first 'synonym ring' of search terms, though not all of these were relevant to the research questions, and in order to identify the relevant articles the title of each article was read and evaluated based on the inclusion and exclusion criteria outlined in Table 1.2. Where there was ambiguity over the relevance of an article, the abstract and on some occasions the paper itself was examined for further clarification.

From the articles retrieved using the first search term, further key words were identified that were different from the originals, which were used to expand and refine the 'synonym ring' (Table 1.3). Search 3 was then conducted with these terms. Search 3 recovered far fewer results and had a high overlap of relevant results with the original search. No new search terms were found in the literature retrieved, therefore no further searches were performed. The final list of papers to be reviewed comprised 98 publications from the literature search, in addition to 16 documents not indexed in the database (e.g. government reports) which were identified through searches of the gov.uk website, and also included when considering the literature. In order to ensure the identified articles provided a comprehensive view of the research area, two previously written review articles were used as a comparison (Bukvova, 2010, De Campos, 2008). The review was conducted in January 2014, and more recent publications supplement the discussion presented in this chapter to inform of the developing literature.

Table 1.2 List of search terms identified from three key publications for Search 2.

Publication and Keywords	(Mittleman et al., 2013)	Precompetitive Consortia
	(Perkmann et al., 2013b)	University-industry relations, Technology transfer, Academic entrepreneurship, Commercialisation, Collaborative research, Academic consulting, Academic engagement, University-industry collaboration
	(Amabile et al., 2001a)	Academic-industrial collaboration, Management science, Organisational sociology, Inter-professional relations, Management research, Intellectual cooperation
Search Term	((((((((University industr* relation*) OR technolog* transfer) OR Academi* entrepreneur*) OR academi* commercialis*) OR collaborat* research) OR academi* consult*) OR academi* engage*) OR university industr* collaborat*) OR precompetiti* consorti*) OR academi* industr* collaborat*) AND English[Language]	
# Results	754	
Inclusion Criteria	Contextual appropriateness, bibliographic terminology coexisting with other commonly used terminology, Journal (Science Translational Medicine, Social Studies of Science, Nature Biotechnology, Journal of Management, Science and Engineering Ethics, Technovation, Research Policy etc.)	
Exclusion Criteria	Not in healthcare/medical sciences. Not relevant to clinical development. Not relevant to research questions, does not meet basic quality criteria (e.g. systematic data collection, intelligible results)	
# Results Filtered	93	

Search terms were used in the initial round of literature identification using the Pearl Harvesting Information Retrieval Framework (Sandieson and Kirkpatrick, 2010).

Table 1.3 Search 3 search terms and results

Publications and Key words	(Eichler et al., 2006)	Academia - pharmaceutical manufacturer collaboration
	(Rasmussen, 2004)	Drug company- academic collaboration
	(McClellan, 1999)	Public-private collaboration Open innovation university industry
	(Draugalis and Coons, 1995)	Academic institution pharmaceutical industry collaboration
	(Angus, 1992)	Research institute pharmaceutical company relationship
	(Stock and Habenicht, 1999)	Cooperative network (term not used due to high-recall, low precision)
Search Term	((((academi* pharmaceutical manufactur* collaborat*) OR drug company* academi* collaboration*) OR public private collaborat*) OR Open innovate* universit* industr*) OR Academi* institution* pharmaceutical industr* collaborat*) OR Research* institute pharmaceutical company* relations* AND English[Language]	
# Results	39	
# Results filtered	17 (12 overlap)	

1.2.1.2 Reviewing the literature

Documents were uploaded to NVivo Version 9.0.3 (QSR International, Cambridge, MA) where they were categorised according to the research questions they addressed. Not all articles were read in full, due to time constraints, however all were scanned to identify key information of relevance to the research question(s). Additionally, not all articles provided additional information to inform the review, and so not all of them are cited in the following discussion.

1.2.2 Results

In this thesis the definition of ‘collaboration’ is based on that suggested by Amabile *et al.* as: “individuals who differ in notable ways sharing information and working toward a particular purpose” (Amabile et al., 2001b). This definition built on previous work by Jassawalla and Sashittal (1998) “the coming together of diverse interests and people to achieve a common purpose via interactions, information sharing, and coordination of activities,” and is in alignment with the definition put forward by Melin and Person (1996), who further discuss the importance of sharing ‘competences and resources’. Sonnenwald (2007) develops this importance by stressing the social context of research collaborations, arguing that in addition to the aims of the collaboration, individual partners may also have their own aims. Collaborations can have a range of conformations and management structures (see Section 1.2.2), and can occur between firms (Dyer and Singh, 1998), between teams (Jassawalla and Sashittal, 1998), or between individual members both within and between institutions and professions (Amabile et al., 2001b, Melin, 2000).

The definition of ‘translational research’ used in this thesis is the one put forward by Sussman *et al.* of “an extended process of how research knowledge that is directly or indirectly relevant to health behaviour eventually serves the public” (Sussman et al., 2006). As outlined in Section 1.1.2, translational research tends to revolve around one of two translational ‘gaps,’ and subsequently

the definition and use of the term 'translational medicine' may differ for different professions. For example, academics may be more concerned with the first translational gap, and clinicians with the second, though this is not always the case. Generally, those individuals concerned with T1 (as outlined in Figure 1.1) aim to harness the knowledge produced through basic research to generate new drugs, devices and treatments for patients. For those focused on T2, the aim is to better use existing or newly developed interventions to assist clinicians and patients in changing behaviours and making more informed choices (Woolf, 2008). These two goals require different skills, expertise and resources, and are both required for the implementation of effective, innovative healthcare, and the transfer of products and skills from 'bench to bedside and back again,' so that knowledge identified through clinical work feeds back to inform basic research (Fontanarosa and DeAngelis, 2003). Translational research has been associated with numerous colloquialisms in the literature, including 'lost in translation,' 'crossing the valley of death,' 'bridging the gap,' 'walking the bridge,' and most commonly 'from bench to bedside' (Butler, 2008, Drolet and Lorenzi, 2011).

1.2.2.1 Collaboration Trends

Several publications highlighted the evolving role of the university in society (Owen-Smith and Powell, 2003, Etzkowitz, 2003). From the two core aims of educating students and generating knowledge, a 'third mission' has developed – to increase interactions between the producers and users of research, with the goal of improving the transfer of new technologies and contributing to regional economic development (Etzkowitz et al., 2000). This 'third mission' has been prioritised in the US through a series of policy measures implemented in the 1980s. These measures aimed to encourage entrepreneurialism (Congress, 1980, Mowery et al., 2001, Congress, 1984, Sussman et al., 2006), and have been described as a key contributing factor to the technological innovation and economic growth in the US over the past 30 years (Hall, 2004, Lee, 2000, Grimaldi et al., 2011). Conversely, the European Commission Report attributes the

poor commercial and technological performance of high-tech sectors in the EU to insufficient interactions between firms and universities (EC, 1995). Conversely, in the mid-1990s the European Commission Report attributed the poor commercial and technological performance of high-tech sectors in the EU to insufficient interactions between firms and universities (EC, 1995). Consequently, the EC commissioned the formation of the Competitiveness and Innovation Framework Programme (CIP), an initiative that aimed to facilitate academia-industry engagement (EC, 2012). In the case of the United Kingdom (UK), government reports emphasised the need to upgrade and diversify manufacturing capabilities in response to globalisation and increasing dependence on the service sector (Porter and Ketels, 2003). Consequently, government efforts focused on exploiting existing advantages in high value-added manufacturing sectors (Willetts, 2013) and on driving the commercial realisation and monetisation of a world-class research base (Hauser, 2010, Lambert, 2003b, Dyson, 2010). Thus, in the US, EU and UK, the realisation of economic growth has been linked to the concept of effectively harnessing university outputs - delivering world-class research to generate 'impact' in society.

One way in which the 'third mission' of producing impact from research has been pursued is through the increased commercialisation of academic research, achieved through activities such as patenting, licensing, and acts of academic entrepreneurship such as the formation of spin-out companies. Many universities have established internal procedures in support of these activities (Thursby et al., 2001), and created structures to facilitate commercialisation, notably technology transfer offices (TTOs) (Siegel et al., 2003a), research 'incubators' (Clarysse et al., 2005) and science parks (Markman et al., 2008, Minguillo et al., 2015). Such methods appear to be increasing academic commercial activities, as a growing literature empirically demonstrates (Thursby and Kemp, 2002, Friedman and Silberman, 2003).

As the expectation of the university to provide returns for the public funds it receives grows, the measure of such 'impact' is also being considered in government evaluations of university performance. The Research Excellence Framework (REF), formerly the Research Assessment

Exercise (RAE), is the primary measure by which universities are evaluated and government funding allocated (Stern, 2016). In 2014, the REF assigned 20% of a university's overall score according to its impact outside of academia. The 'impact' measure was generally positively received, with several calls to increase its weighting to 25% for the next REF (Dowling, 2015, Witty, 2013, ABPI, 2016). However, some of the metrics used were criticised as 'too narrow' to capture the breadth of impact activities across the full range of subject areas. (Wolff, 2013) (Greenhalgh and Fahy, 2015). Indeed, the measures of 'commercialisation' were patents, licenses and spin-outs (HEFCE, 2015), metrics which are increasingly discussed as 'flawed' in the literature as true reflections of technology transfer and social impact (Nelson, 2009). The reason for this is because these activities are perceived as transactional in nature (e.g. an exchange of funds for IP), thus requiring limited genuine knowledge exchange or even interaction between universities and outside sources, notably firms (Giuri et al., 2007). Furthermore, 'counting productivity' in terms of patents and licenses neglects numerous other knowledge exchange channels (Giuri et al., 2007, Murray, 2004), and captures a very small proportion of collaborative activity. This is especially true because scientists' formal participation in technology transfer is highly skewed, with patenting academics accounting for less than 2% of all publishing academics in one field in the UK, Belgium and Germany (Meyer, 2006). Therefore, the focus of commercialisation and academic engagement with industry is shifting towards more collaborative activities, such as joint research projects, which not only occur more frequently than patenting, licensing, and spin-outs (D'Este and Patel, 2007), but are perceived as more important channels for knowledge transfer by both academics (Agrawal and Henderson, 2002) and industry (Cohen et al., 2002).

This shift towards 'genuine' collaboration, where the interactions between parties involve a greater degree of exchange, is highlighted by Milne and Malins' report, which identifies a shift in partnership models in the US from more transactional (e.g. unrestricted grants, fee-for-service) to more involved types of collaboration (e.g. the formation of academic drug discovery centres and the use of corporate venture capital funds) (Milne and Malins, 2013). These findings should

be placed within the wider observation that academic entrepreneurship is both a demand pull and a technology push phenomenon (Rothaermel et al., 2007). On one hand, as demand for technological innovations increased, universities become a key source for innovation (Von Hippel, 1986), especially in biotechnology (Zucker et al., 1998) and nanotechnology (Zucker and Darby, 2005). On the other hand, universities over time begin proactively transferring technology to industry, in part due to reductions in their public funding (Thursby et al., 2001). Thus, Milne and Malins suggest future trends will bring collaborative partners even closer, with increased use of risk-sharing and competitive grant models (2013).

In the UK, a similar trend has been identified, as models of collaboration tend towards closer interactions between partners. Data from the Association of the British Pharmaceutical Industry (ABPI) show a decrease in academia-industry collaborations at a student level, with the number of undergraduate industrial placements down by 53% between 2007 and 2013, and a fall in the number of PhD and post-doctoral grants by 11% and 34%, respectively, between 2003 and 13 (ABPI, 2014). However, the number of publications co-authored by industry and academia - arguably a more robust measure of collaboration (Tijssen, 2011) - has consistently increased in the UK, Canada, Italy and Norway since the 1980s (Calvert and Patel, 2003, Abramo et al., 2009, Lebeau et al., 2008). Furthermore, unlike the numbers of studentships, the use of university-industry co-publication propensity indicators is found to have a significant positive relationship with a university's technology commercialisation outputs (Wong and Singh, 2013).

The past 30 years have heralded a change in university drivers and an increase in levels of collaboration in the UK (Calvert and Patel, 2003, McKelvey and Holmén, 2010). In order to understand the current landscape of academia-industry collaboration in the UK, a snapshot is captured in the recent Dowling review (2015). Of 12,240 collaborations identified from 91 universities, the research area with the highest proportion of collaborations was engineering and physical sciences, with 51% of all collaborations (Dowling, 2015). It is perhaps this distribution that is the reason why the majority of published research considered in this scoping review

concerns the field of engineering (D'Este and Patel, 2007, Banal-Estañol et al., 2015) (Roessner et al., 2004, Bruneel et al., 2010). Life sciences comprised 28% of all collaborations, consisting of clinical medicine (which contributed 51% of all life science collaborations), biological sciences (26%), health professions and services (19%), and agriculture, veterinary and food science (4%).

While the aims and purposes of these collaborations were not explored in the Dowling Report, a comparable study investigated more than 3000 industry grants awarded to medical schools in the US. Of these, 75% of grants were for joint clinical trials (a similar majority as found in the Dowling report), 14% were for the purpose of public health priority studies, and 11% were for health research and education projects (Milne and Malins, 2013). Of the health research and education projects, 30% were classified as basic research, and 15% were classified as translational research (1.7% of all industry grants to academic medical centres). This highlights a propensity for industry to fund clinical research more commonly than basic research. One potential reason for this is that clinical research represents a more straightforward 'transaction', industry pay universities to conduct trials on their behalf.

Studies have identified particular features common amongst collaborating academics and companies (D'Este and Fontana, 2007), and these have been collated in this scoping review and summarised in Table 1.4. These features can occur at the levels of individual collaborators, research departments or institutions. For example, the size of the department seems to have a 'u-shaped' correlation with collaboration, with medium-sized departments at a disadvantage in comparison to small and large departments (D'Este and Patel, 2007). However, for simplicity they have been listed as pertaining to either the company or the academic.

Some of these features have been found to have a greater impact on collaboration than others. For example, academics' previous involvement in collaboration is an extremely strong predictor of future frequency and variety of interaction with industry (D'Este and Patel, 2007). In one study, 80% of collaborations examined has partners who had worked together previously, and these collaborations were positively correlated with the satisfaction of collaborative outcomes

(Pertuzé et al., 2010). The impact of the age of the academic on propensity to collaborate was less certain, with different papers presenting contradicting impacts. While some studies found a positive correlation between age and propensity for collaboration when controlled for seniority (Haeussler and Colyvas, 2011, Link et al., 2007), other studies find a higher rate of collaboration among younger researchers as the behaviour is legitimised over time (Bercovitz and Feldman, 2008). The relationship between certain features is also explored in the literature. For example, the lower proportion of female academics in senior positions is likely an important factor in why collaborations occur more commonly amongst male academics even though female and male academics are equally likely to collaborate (Abramo et al., 2013, Abramo et al., 2014). Furthermore, a range of empirical studies demonstrates a correlation between industrial engagement and academic success. Several studies show that academics who are listed as patent holders publish more and better papers than their non-patenting colleagues (Azoulay et al., 2007; Fabrizio and Di Minin, 2008). Furthermore, academics who collaborate with industry tend to have higher levels of non-industrial funding, including government grants (D'Este and Patel, 2007). Results from a study in Norway noted that academics in all fields who had received industry funding reported more frequent research collaborations with colleagues in their own departments, as well as across different research institutions both nationally and internationally. This study also showed that academics who had conducted research resulting in patents, commercial products, spin-outs and consultancy produced more publications on average than similar academics who had not conducted such research (Gulbrandsen and Smeby, 2005). It is not clear from the literature, however, whether these academics are prolific because of their industrial interactions, or whether they have industrial interactions because they are more prolific.

As the literature on collaboration grows and the field develops, contradictions emerge as to the actual impact of several factors previously thought to be important to the success of a collaboration. For example, Pertuzé *et al.* (2010) conducted a 3-year study across 25 firms and multiple industries, and identified several factors which they claim have no impact on the success

of a collaboration, including geographical proximity, which contradicts research on science parks and bioclusters (Ponds et al., 2007, Laursen et al., 2011), and the presence of an executive ‘champion’, which contradicts work by Kneller *et al.* and other groups across various fields who discuss the importance of such individuals as ‘boundary spanners’ (Wohlin et al., 2012, Geiger, 2008, Kneller et al., 2014b). It is therefore difficult to confirm or deny the impact of such factors entirely, especially due to the differences in cultures, environments and incentives across academic disciplines (Meyer-Krahmer and Schmoch, 1998, Kenney and Goe, 2004). Thus, to truly understand their importance, each factor will need to be explored within the specific context of the collaboration investigated, rather than extrapolating between fields. For example, when investigating clinical research, a key barrier that should be considered is fundamental mistrust of industry by clinicians (Kesselheim et al., 2012), and vice versa (Fisher, 2008). The perception of workers in the UK’s National Health Service (NHS) is that industry is motivated by profit ahead of patient benefit and that this can bias the results of clinical trials (Trotman, 1987). This perception may be a result of several publications showing that results from industry-supported studies have been associated with more favourable outcomes than non-industry-supported trials (Watkins et al., 2003). For example, in a sample of more than 500 trials investigating five major classes of drugs, 85% of industry-supported trials were positive compared with only 50% of government-funded trials (Goldacre, 2013). This concern, regarding the influence of industry, is highlighted by some leading medical journals (e.g. the British Medical Journal) which debate the legitimacy of publications from industry-sponsored trials (Smith et al., 2014). This issue is particularly relevant to translational medicine due to its high proportion of clinician-scientists and involvement of NHS workers.

Table 1.4 Features of academics and companies that participate in collaboration.

Features of academic collaborators	Reference
Affiliation with special centres, such as research centres, within the university	(Perkmann et al., 2013a)
Research quality of university (better quality, more collaborations)	(D'Este and Iammarino, 2010)
Group-level norms in academia – the values and priorities of colleagues (more likely to collaborate if patenting/awards valued in addition to traditional academic values)	(Haeussler and Colyvas, 2011) (Perkmann et al., 2013a)
Academic seniority (senior academics are more likely to collaborate)	(D'Este and Patel, 2007)
Department characteristics (i.e. size, research income, research quality)	(D'Este and Patel, 2007)
Amount of public funding received for non-collaborative research (i.e. more funding received, more likely to collaborate)	(D'Este and Patel, 2007)
Gender (male academics more likely to collaborate)	(Boardman and Corley, 2008) (Abramo et al., 2013)
Previous experience with commercialisation, patenting or venture creation (increases the likelihood of academics' participation in collaborative activities)	(D'Este and Patel, 2007, Bekkers and Freitas, 2008)
Peer esteem (well considered by peers more likely to collaborate)	(Bruneel et al., 2010)
Features of industrial collaborators	Reference
Engaged 'boundary spanning' personnel	(Wohlin et al., 2012, Kneller et al., 2014a, Geiger, 2008)
Extensive use of students	(Ankrah et al., 2013, Kneller et al., 2014b)
Absorptive capacity (ability to assimilate knowledge)	(Cockburn and Henderson, 1998)
Close proximity to (top-tier) university/presence in 'Science park'	(Lindelöf and Löfsten, 2004) (Laursen et al., 2011) (D'Este and Iammarino, 2010)
Industrial drivers (i.e. if R&D driven industry more likely to use universities as a knowledge source, also if knowledge search strategies tend to be external or more 'open')	(Laursen and Salter, 2004)
Company size (start-ups more likely to collaborate, large firms more likely to use knowledge)	(Kneller et al., 2014b, Cohen et al., 2002)

1.2.2.2 Types of university-industry interactions

Academia-industry collaboration can occur in many different forms, each of which may have different characteristics and result in different outputs. In order to capture the diversity of these interactions, several academic groups have put forward 'typologies'. These typologies, presented in Table 1.4, have certain commonalities in structure, however differ according to the context in which they were developed and used. While such differences in typology makes comparing results across data sets more challenging (for example, one issue that has been highlighted in the literature is difficulty in comparing the *organisation* and *management* of different interactions (Perkmann and Walsh, 2007)), this specificity enables a relevant context-specific analysis to occur. This is important as evidence from several studies suggests that the type of collaboration employed can vary according to the field of research (Meyer-Krahmer and Schmoch, 1998, Schartinger et al., 2002, Faulkner and Senker, 1994, Rappert et al., 1999) and by country of origin (Kneller et al., 2014b). Furthermore, the types and goals of collaboration were found to differ according to whether the research is basic or applied. In scientific fields primarily conducting basic research (also referred to as 'pure' or 'fundamental' research) such as biology and chemistry, industrial partners are primarily interested in the commercial implications of a collaborative project, which could subsequently be developed by their in-house R&D team. By contrast, in more applied fields such as engineering or computer science, industry tend to initiate collaborations with the aim of solving a particular technical issue (Kock et al., 2000). This creates a different model of communication, as pointed out by Stewart (Stewart et al., 1999), where collaborations in basic science utilise a 'network' model of innovation, placing reduced emphasis on the direct commercialisation (linear model) of new knowledge created by academics, while instead highlighting the importance of multi-directional knowledge transfer between researchers.

In a study of university-industry R&D collaboration in three example countries, it was shown that collaborations in the US and the UK tend to have similar features, in contrast to collaborative

activities in Japan. These differences were attributed to variations in the nature of higher education, prevailing cultural norms, and the dominant legal and economic structures (Rahm et al., 2000), and may provide insight into the role of environmental and cultural factors that impact upon collaboration, especially considering Japan's comparatively high patenting rate (Motohashi and Muramatsu, 2012).

The interactions outlined in Table 1.5 have been categorised by other authors according to various aspects of the collaboration. For example, categorising types of collaboration according to resource deployment, duration, and the degree of formalisation of agreements can be indicative of the experiences and outcomes for the collaborations for both partners (Schartinger et al., 2001, Schartinger et al., 2002, Bonaccorsi and Piccaluga, 1994). Due to the heterogeneity of typologies used across the literature (Table 1.5), these categorisations are useful, if imperfect, as a basis for comparison between studies. However, establishing a well-fitting, common typology (as was attempted for university spin-out companies (Pirnay et al., 2003)) could enable easier assessment and comparison of different collaborations across multiple areas and countries, not only in terms of structure but also operation and output. This could be especially useful due to the role of informal linkages between academia and industry, which, despite their importance, are not as well-researched as more formal interactions such as contract research and technology transfer due to a lack of available data (Stewart et al., 1999).

.

Table 1.5 Different typologies used to categorise relationships between academia and industry.

Paper	Typology	Notes
(D'Este and Patel, 2007) - Surveyed 4337 academics across Engineering, Maths, Materials, Physics, Chemistry and Computer Science - Individual characteristics of the researcher influence the frequency and variety of interactions more than departmental or institutional factors.	Consultancy & contract research: <i>Consultancy work</i> (commissioned by industry, not involving original research) <i>Contract research agreements</i> (commissioned by industry and undertaken only by university researchers)	56.3% of academics had engaged in this type of research
	Joint research: <i>Joint Research agreements</i> (involving research undertaken by both parties)	44.6% of academics had engaged in this type of research
	Training: <i>Postgraduate training in company</i> (e.g. joint supervision of PhDs); <i>Training company employees</i> (through course enrolment or personnel exchanges)	42.5% of academics had engaged in this type of research
	Meetings/ conferences: Attendance at <i>Industry sponsored meetings</i> ; Attendance at <i>Conferences</i> with industry and university participation	65.0% of academics had engaged in this type of research
	Creation of physical entities (e.g. spin-outs): Setting up <i>spin-off companies</i> ; <i>Creation of physical facilities</i> with industry funding (including campus laboratories, incubators and cooperative research centres)	20.8% of academics had engaged in this type of research
	Secondments	[surveyed but not included due to low response]
	Electronic networks	
(Kneller et al., 2014b) - Interviews with 90 companies in Japan, Canada, UK and USA - Focus on IP issues and publication freedom	Collaborative (or commissioned) research	Vast majority of 'Collaborative Research' were joint research projects, constituting 80-90% of all collaborations, and was further sub-categorised into: start-ups; applied research not involving start-ups; and blue-sky research (comprising both 'light blue' (where the problem is relatively defined) and 'dark blue' (projects are exploratory research). The vast majority of all collaborations were engineering related.
	Training to meet needs of company's industry	
	A license was the main aspect of the interaction	
	Engaging universities as clients for company's business	
	Recruitment only	
(Bonaccorsi and Piccaluga, 1994) Not mutually exclusive, i.e. one interaction may	Business development, technology commercialization	The main variable for the taxonomy is the organisational resource deployment, in terms of personnel, equipment, and financial resources that the two parties are willing to commit to the relation. The six types of relationship identified here
	Personal Informal Relationships (spin-outs, individual consultancy, joint lectures, personal contact)	
	Personal Formal Relationships (Student internships/sandwich courses, joint student supervision, sabbaticals, use of facilities)	
	Third Party (Institutional consultancy, government agencies, TTO)	

fall into multiple categories.	Formal Targeted Agreements (Contract research, patent/licence agreements, co-operative research projects, equity holding in companies by academics, exchange of research materials, training programs, joint research programmes)	exhibit an increasing level of organisational involvement (top to bottom). The types are also analysed in terms of a) The organisational resource involvement of the university b) The length of the agreement c) The degree of formalisation
	Formal Non-Targeted Agreements (Endowed chairs, advisory boards, industry funding university posts, industrially sponsored R&D in universities, research grants)	
	Creation of Focused Structures (Association contracts, incubators/innovation centres, science parks, consortia, mergers, subsidiary owners)	
(Schartinger et al., 2001) • Survey of University departments and Innovative firms in 1998/99	Joint research projects	Most common type of activity for university departments was “Joint supervision of Ph.D.s and Masters Theses by university and firm members”, with 38% of departments engaging in this at least once. The most common type of interaction for industry was “employment of graduates”, with 67% of firms engaging in this at least once.
	Contract research	
	Joint supervision of PhD and Masters Theses by university and firm	
	Employment of university researchers in the business sector	
	Lectures by firm members at universities	
	Joint Publications	
	Training of firm members	
	Spin-off formations of new firms	
	Temporary movement of university members to the business sector	
	Employment of graduates	
	License agreements	
	International research networks	
(Schartinger et al., 2002) • Survey of faculty from all 12 Universities in Austria in 1995	Employment of graduates by firms	Analyses interactions in terms of a) Formalisation of interaction b) Transfer of tacit knowledge c) Personal (face-to-face) contact Research shows 32% of research projects with industry are in Technical Sciences, 25% in Natural Sciences, and 19% in Medicine Group interactions into four categories: a) joint research (including joint publishing) b) contract research (including consulting, financing of university research assistants by firms), c) mobility (staff movement between universities and firms, joint supervision of students) and d) training (co-operation in education, training of firm staff at universities, lecturing by industry staff)
	Conferences or other events with firm and university participation	
	New firm formation by university members	
	Joint publications	
	Informal meetings, talks, communications	
	Joint supervision of Ph.D. and Masters theses	
	Training of firm members	
	Mobility of researchers between universities and firms	
	Sabbatical periods for university members	
	Collaborative research, joint research programmes	
	Lectures at universities help by firm members	
	Contract research and consulting	
	Use of university facilities by firms	
	Licensing of university patents by firms	
	Purchase of prototypes developed at universities	

	Reading of publications, patents etc.	
(De Campos, 2008) • Review	Training of human resources	Discusses mechanisms involved in university-industry links, and how these change according to the stage of development of the economy (i.e. in developing economies the flow of human resources from universities is more important, in 'advanced countries' contractual agreements and social networks are more important.
	Social networks and informal contacts	
	Formalised contractual agreements	
(Meyer-Krahmer and Schmoch, 1998) • Responses from a survey of German academics	Collaborative research	Ranked from highest to lowest importance from the perspective of academics.
	Informal contacts	
	Education of personnel	
	Doctoral thesis	
	Contract research	
	Conferences	
	Consultancy	
	Seminars for industry	
	Scientist exchange	
	Publications	
	Committees	
(Cohen et al., 2002) • Carnegie Mellon Survey on industrial R&D • Describes 'channels of information flow' as opposed to types of interaction	Publications/reports	Ranked from most important at top to least important at the bottom (for industry) "The most important channels of information flow between public research institutions and industrial R&D labs are the channels of open science, notably publications and public meetings and conferences. These channels are relatively decentralised in the sense that they do not typically reflect formal institutional links."
	Informal interaction	
	Public meetings or conferences	
	Contract research	
	Consulting	
	Joint or cooperative ventures	
	Patents	
	Personnel exchange	
	Licences	
	Recently hired graduates	
(Perkmann and Walsh, 2007) • Reviews literature to determine typology	Research Partnerships: Inter-organisational arrangements for pursuing collaborative R&D	Proposes a framework for capturing different dimensions of these links based on extent of 'relational involvement' (RI) between universities and industry: a) High RI is where links are based on relationships: individual and teams from both institutions work together on specific projects to produce common
	Research Services: Activities commissioned by industrial clients including contract research and consulting	
	Academic Entrepreneurship: Development and commercial exploitation of technologies pursued by academic inventors through a company they (partly) own	

	Human Resource Transfer: Multi-context learning mechanisms such as training of industry employees, postgraduate training in industry, graduate trainees and secondments to industry, adjunct faculty	outputs (e.g. Research Partnerships, Research Services)
	Informal Interaction: Formation of social relationships and networks at conferences, etc.	b) Medium RI is when links are based on mobility (Academic entrepreneurship and human resource transfer)
	Commercialization of Property Rights: Transfer of university-generated IP (such as patents) to firms, e.g. via licensing	c) Low RI is when links are based on transfer (Commercialisation of IP)
	Scientific Publication: Use of codified scientific knowledge within industry	Use of scientific publications, conferences and networking can accompany all forms.
(Milne and Malins, 2013) - Report on partnerships in biopharmaceutical R&D - Also described are 'frequency of use'	Unrestricted research support	Widely used
	Relationship between company and PI	Widely used
	One company – one university	Widely used
	Fee for service	Widely used
	Venture capital	Increasingly used, evolving
	Corporate mini-lab/ "bioclusters"	Increasingly used
	University consortium	Rare, but increasingly used
	Funding of large institute	Rare, but increasingly used
	Competition	Emerging
	Industry/ government funded precompetitive research centers	Emerging
	Academic Drug Discovery Centers (ADDGs)	Increasingly used
	Risk-sharing models	Emerging
(Chin-Dusting et al., 2005)	Consultations and fee for service, including contract research outsourcing.	Relationship/alliance
	Competitive grants sponsored by industry.	Relationship/alliance
	Industrial sponsorship of training and education programmes.	Relationship/alliance
	Industrial sponsorship of investigator-led research	Collaboration
	Institute-institute liaisons.	Collaboration
	Academia, industry and the government.	Collaboration

1.2.2.3 Positive aspects of collaboration

An important determinant academia-industry interactions are the perceived benefits for the participants. In this section, the factors supporting the formation or fulfilment of collaboration, including motivations, advantages and beneficial outcomes, are discussed for both academia and industry.

1.2.2.3.1 Academia

The motivations for, and advantages of, collaboration for academics have been addressed in the literature in several ways. Lopez-Martinez *et al*/identify such factors at structural, institutional, and individual levels (López - Martínez et al., 1994). Structural elements comprise economic, political and technological factors, institutional elements stem from the particular features of the institution, and individual factors describe features of the individual researchers. Alternatively, Valentin *et al*/divided benefits and motivations into separate categories, discussing benefits in terms of the financial, technological and strategic, and motivations in terms of the educational, political, and epistemological. Ankrah *et al*. (Ankrah et al., 2013) subdivide motivations according to the six contingencies identified by Oliver (Oliver, 1990): necessity, reciprocity, efficiency, stability, legitimacy and asymmetry. They go on to separate the beneficial outcomes of collaboration into three broad categories – economic, institutional, and social. Many of these studies consider the motivations of universities and companies as entities, however, in this scoping review an understanding of the individual benefits and motivations for collaboration is sought.

Table 1.6 highlights the most commonly cited positive aspects of collaboration for academics. These positive aspects have been categorised based on whether the benefits are primarily received by the individual PI (e.g. in additional funding for their research

group), their research programme or institution (e.g. in the generation of new knowledge) or society in general (e.g. through accelerated technology development). This distinction was used as it provides insight into motivations and benefits across three levels – the academic, the university, and the government. The government was included both because it is the primary funding source for universities, and because this thesis seeks to inform government policy.

The primary benefit at an individual level appears to be financial, where researchers access increased funds directly from industry, through eligibility for grants which require industrial partners, and can gain personal income through consulting. Collaborating with industry can improve the perception and reputation of the participating academics both internally and externally (Moutinho et al., 2007; Owen-Smith and Powell, 2001; van Rijnsoever et al., 2008), and provides valuable insight into cutting edge research and industrial trends. It is not the case, however, that the greater the level of industrial engagement the better. In their analysis of collaborating academics in UK engineering departments, Banol-Estanol *et al* demonstrate that while researchers with no industry interaction are less productive than those with a small degree of collaboration, higher levels of interaction (comprising 31% or more of total research funding) negatively affect research productivity in terms of publication output (Banal-Estañol et al., 2015). Furthermore, this increase in productivity was only found to be significant when the research is applied rather than basic in nature. While this trend has thus far only been identified for publications, it may hold true for other benefits of collaboration, and raises the question of how much collaboration is “too much”.

Institutions benefit from increased applicability of their research and exposure of students to real industry questions and approaches. Collaborations may also result in the funding of new centres within the university, in addition to reputational gain. Furthermore, it appears that universities gain from charging full overheads to industry.

The Dearing Report highlighted a deficit in university funding of £110 million per annum to meet the full costs of research of grants awarded by Research Councils (Dearing, 1997). Consequently, from 2006, the Government agreed that Research Councils should pay 80% of the full economic cost (FEC) of projects they fund. However, such stipulations over FEC do not apply to funding from charities, and as highlighted, for example, on the University of Oxford website: “Oxford has secured an increasingly large volume of grants from charities, most notably to support research in medicine and the biosciences. These grants have made a major contribution to the University's research effort, but have also brought attendant difficulties because they do not in general cover the full costs of research” (UAS, 2010). Thus, funding from industry is increasingly required to compensate for shortfalls in funding from other sources, and is therefore important for the continued sustainability of universities. Transparency Review data for 2007/08 indicates that around 75% of FEC is being recovered on contracts with industry. However, as discussed in Section 1.2.2.4, the costs of these overheads is prompting general concern among businesses and government about the increasing costs of research in the UK (Alexander, 2009). The CBI Inter-Company Academic Relations Group (ICARG) asserts that the UK is the 'most expensive country in the world for Research Personnel', i.e., the cost of paying one member of research staff is higher in the UK than any other country. This may make the UK an unattractive location for developers, and consequently it is suggested that UK-based companies are placing an increasing proportion of their research budgets overseas (Alexander, 2009).

Table 1.6 Positive aspects of collaboration in academia

Positive Aspects in academia	
For Academic	Additional research income from industry (D'Este and Patel, 2007, Perkmann et al., 2013a)
	Improved funding opportunities from non-industry sources (D'Este and Patel, 2007, Ankrah et al., 2013)
	Secure funds for lab equipment (Lee, 2000)
	Gaining further insight into their own research areas (Lee, 2000, Poyago - Theotoky et al., 2002)
	Increased visibility inside and outside of institution (Ankrah et al., 2013)
	Enhanced career opportunities (Ankrah et al., 2013)
	Better business understanding and greater links with industry to exploit this (via feedback on research decisions, test application of idea/theory) (Ankrah et al., 2013)
	Recognition among peers (Siegel et al., 2003b)
	Potential for high impact publications (Siegel et al., 2003b)
	Consulting income (Pronk et al., 2015b)
	Contribution to creation of new intellectual property (Ankrah et al., 2013)
	Awareness of trends in industry (Pronk et al., 2015b)
	Interesting, provides personal satisfaction (Ankrah et al., 2013)
For Research Programme/ University	New financial sources, overheads (Valentin and Maria, 2000) (Maglaughlin and Sonnenwald, 2005)
	Expose students/staff to applied technologies/problems and provide career opportunities (D'Este and Perkmann, 2011) (Ankrah et al., 2013) (Pronk et al., 2015a)
	Increased applicability of research (D'Este and Patel, 2007)
	Exposure to current industry issues, creating new research avenues. (D'Este and Patel, 2007)
	Inspiration of academic research by application-derived questions (Pronk et al., 2015b)
	Access to industry skills and facilities (Ankrah et al., 2013, D'Este and Patel, 2007)
	Potential for funding centres/consortia (Pronk et al., 2015b)
	Access to additional capacity for research (López - Martínez et al., 1994)
	Enhancement of reputation/institutional prestige (Valentin and Maria, 2000)
For Society/ Government	Increased economic development (Valentin and Maria, 2000)
	Potential improvements to education/curriculum (Pronk et al., 2015a, Valentin and Maria, 2000)
	Strengthening of regional innovation system (Poyago - Theotoky et al., 2002)
	Service to the community/society (Ankrah et al., 2013)
	Acceleration of technological development/diffusion (Poyago - Theotoky et al., 2002)
	Pooling expertise for complex problems (Birnholtz, 2007)
	Higher productivity from research funding (CH, 2012)

Government and society benefit from many of the factors highlighted in Section 1.2.2.1, including increased economic development (especially in surrounding regions), in getting an increased return from investment in research and from the acceleration of technological development (Table 1.6).

1.2.2.3.2 Industry

The literature on the industrial experiences of collaboration is less extensive, especially on an individual level, due to the lack of individual autonomy in industrial environments, and to the poor availability of private-sector data (Stern, 2004). However, the literature is growing, and findings from Siegal *et al* (Siegel et al., 2003a) identify the primary motivation for firms to collaborate as 1) financial gain, and 2) the desire to maintain control of proprietary technologies through exclusive licensing agreements. Lee et al found that firms collaborate in order to access new knowledge to drive internal innovation activities, and to recruit highly-skilled personnel (Lee, 2000). Firms seek partners who are academically excellent and within reasonable geographic proximity (Mansfield, 1998). As highlighted in Section 1.2.2.1, the relative importance of positive aspects may vary according to the size of collaboration, the degree of involvement and the use of mediating personnel (Kneller et al., 2014a). As with academics, members of industry benefitted more from genuine partnership activities as opposed to more transactional activities such as contract research (Perkmann et al., 2013a)

Table 1.7 highlights the most commonly mentioned motivations and advantages for industry. These have been characterised according to whether the benefits are a) ‘inward looking’, i.e. experienced internally by improving the internal resources of the company, for example, by enhancing company skills, or b) ‘outward looking’, i.e. experienced

externally in terms of the position of the company relative to competition, e.g. exclusivity or enhanced perception (Simard and West, 2006).

The inward-looking benefits tend to either be project-specific (e.g. in mitigating risk, reducing costs, and solving specific issues) or about the more general acquisition of skills and knowledge. Industry-funded research within academia aims to complement the research performed in-house (Owen-Smith and Powell, 2003). However, firms, especially SMEs, need to possess adequate 'absorptive capacity' to be able to integrate the knowledge obtained from universities into their own innovation processes (Cohen and Levinthal, 1989). Outward-looking benefits tend to concern either increased visibility and influence (of policy, opinion and perception), or securing exclusivity, thereby preventing competitors from accessing the same technology.

Table 1.7 Positive aspects of collaboration for industry

Positive aspects of collaboration for industry	
"Inward" looking	Risk-sharing projects with academic groups (Bonaccorsi and Piccaluga, 1994)
	Solutions to specific problems (Ankrah et al., 2013)
	Bypassing need for large investment in internal facilities where rates of utilisation are unpredictable (Bonaccorsi and Piccaluga, 1994)
	More flexibility on entering new areas due to reduced in-house commitment (Valentin and Maria, 2000)
	Reduced uncertainty on new technological trajectories (Autio et al., 1996)
	More cost-effective than similar research in-house (Ankrah et al., 2013)
	Potential to commercialise university-based technologies and benefit from serendipitous results of research activity for financial gain (Bonaccorsi and Piccaluga, 1994)
	Advance access to scientific breakthroughs and state-of-the-art information (Bonaccorsi and Piccaluga, 1994)
	Access to highly qualified human resources already skilled in state of the art research activity (Bonaccorsi and Piccaluga, 1994, Pronk et al., 2015a)
	Access to specialised, world-leading skills and resources (Pronk et al., 2015a)
	Improved understanding of existing technologies through complementary know-how and training and support for in-house skills (Kneller et al., 2014b)
	Stimulating internal R&D creativity of in-house research personnel through exposure and high level scientific exchange with academics (Bonaccorsi and Piccaluga, 1994)
"Outward" looking	Enhanced image and reputation with the industrial community (Ankrah et al., 2013)
	Maintain control of proprietary technologies (Siegel et al., 2003a)
	To foster community relations (Molina et al., 1997)
	Generation of new publications (Molina et al., 1997)
	Improved corporate image (Bonaccorsi and Piccaluga, 1994)
	Provision of competitive advantage (Ankrah et al., 2013)
	National incentives for developing relations e.g. tax exemptions, public grants (Ankrah et al., 2013)
	Enhances ability to influence policy (Ankrah et al., 2013)
	Produce more publications (Ankrah et al., 2013)
	Making access to knowledge more difficult for competitors (Bonaccorsi and Piccaluga, 1994)

1.2.2.4 Negative aspects of collaboration

As more universities and companies engage in collaboration, the issues and barriers hindering collaboration are increasingly scrutinised in the literature (Hall et al., 2001, Salter, 2009). A typology of barriers identified by Bruneel et al (Bruneel et al., 2010) distinguishes ‘orientation’ barriers (the compromises to cultural norms and ideals) from ‘transaction’ barriers (the costs of dealing with the rules and regulations of the partner). In this research, a distinction has been made between the environment of the institution, and the culture of academia in its entirety, in order to allow the emergence of institutional, and even departmental factors that enhance and inhibit collaboration. For example, while it may be the case that industrial collaboration is negatively perceived in one institution, this may not be the case in another (and this is therefore an institutional factor), whereas the academic drive to publish, a cultural factor, would be expected across all institutions (Partha and David, 1994).

Table 1.8 collates the most frequently identified barriers according to whether they are encountered at a cultural, institutional or process level. The ranking or prioritisation of barriers according to impact is not possible given the diversity of investigations and research settings included here. However, within individual studies, key trends do emerge. In considering the barriers associated with the collaboration process, IP arose as an issue in numerous studies - research by Hall *et al*/identified conflicts over intellectual property (IP) as presenting ‘insurmountable’ barriers to collaboration for 30% of partnerships examined. Furthermore, in a series of interviews, 80% of industrial respondents perceived “Bureaucracy and inflexibility of university administrators” and “University too aggressive in exercising intellectual property rights” as key barriers to collaboration (Siegel et al., 2003a). In a survey of 210 life-sciences companies by Blumenthal *et al*, IP was the third most commonly experienced barrier, with most companies citing “university bureaucracies that made it too complicated to conclude an

agreement” as a key difficulty (Blumenthal et al., 1996). The role of bureaucracy is important here, and the involvement of technology transfer offices (TTOs) can aid or impede collaboration. Academics’ decisions to disclose new inventions to TTOs are influenced by their perceptions of the advantages of patent protection. These incentives to disclose are enhanced or hindered by the perceived costs of interacting with TTOs and institutional environments that are supportive, indifferent or discouraging of the concurrent pursuit of academic and commercial activities (Owen-Smith and Powell, 2003). It would be logical to assume that more supportive institutional environments are more likely to have TTOs and transfer more technologies, but this is not always the case. Some studies argue that policies designed to encourage universities to commercialise their research are blocking rather than facilitating collaboration (Siegel et al., 2003a, Valentin and Jensen, 2007). Indeed, authors argue that IP and contracting barriers have become more prevalent as university administration take more aggressive stances during negotiations (Hertzfeld et al., 2006), causing academics to circumvent TTOs and engage directly with industry partners (Siegel et al., 2004). Indeed, it has been argued that university access to IP rights has not only made technology transfer more expensive, complicated, and time-consuming for companies, but that much of the technology transfer occurring as a result of university claiming IP rights would have happened regardless (Nelson, 2001). This barrier may be aggravated in circumstances where the importance of IP is heightened, for example, in the case of translational medicine, where patents play a role in determining both drug pricing strategies and even company value in biotechnology and pharmaceutical companies (Correa, 2004, Frank and Salkever, 1997, Chen and Chang, 2010).

IP is widely written about as a tangible and commonly encountered barrier. However, the institutional environment within which an academic operates can also have a substantial effect. As discussed in Section 1.2.2.1, factors such as the size of the research department affect the likelihood that an academic will collaborate, as does the quality of the university

and its proximity to industry hubs such as science parks (Laursen et al., 2011). Features of the institution itself can also create environments that are more or less conducive to collaboration. In Merton's idealised account of the institutional norms of science, conflicts in values such as: publication of research, choice of research topic and long-term vs short-term orientation, were observed for scientists and engineers in academia and industry (Merton, 1973). Accordingly, differences in values have created different environments in which academia and industry, with potentially conflicting norms and practices. Some of these differences are highlighted in Table 1.9 by comparing research and development (R&D) in academia and industry. Naturally, these differences can create tensions between collaborating partners, especially where expectations have not been managed and trust not established (Siegel et al., 2003e, Tartari et al., 2012).

In terms of strategies to address these barriers, collaborations that operate within 'common ground' as identified by Ivascu *et al* were associated with positive experiences (Ivascu et al., 2016), though transactional barriers (such as conflicts over IP) were still encountered. A study by Bruneel *et al* (2010) identified three factors needed to mitigate barriers to collaboration: experience, communication and trust. Though only the last of these, the existence of inter-organisational trust, was effective in overcoming transactional barriers. These strategies highlight the importance of selecting an appropriate collaboration partner with which to build a relationship (Barnes et al., 2002).

Table 1.8 Barriers to academia-industry collaboration

Type	Negative aspect
Process	Conflicts over intellectual property ownership (Hall et al., 2001, Anatan, 2009, Siegel et al., 2003b, Bubela et al., 2012)
	University bureaucracy makes it difficult to reach agreement on contracts (Blumenthal et al., 1996)
	Inadequate technology transfer office (Siegel et al., 2003d)
	Industrial liaison offices tend to oversell research or have unrealistic expectations (Bruneel et al., 2010)
	Restrictions/delays on publications and dissemination of research outcomes (Kneller et al., 2014b)
	Absence of established procedures for collaboration (Wilson, 2012)
	Absence/low profile of industrial liaison officers and/or technology transfer office within university (Siegel et al., 2003b, Witty, 2013) (Bruneel et al., 2010)
	Rules/regulations imposed by university or government funding agencies (Salter, 2009)
Institutional/ social environment	Concerns about perceived bias/conflict of interest from department/colleagues/other (Harbin, 2014, Kneller et al., 2014b, Ankrah et al., 2013)
	Diversion of energy and commitment of staff away from core activities.(Ankrah et al., 2013)
	Lack of suitable government funding programs (Witty, 2013)
	Concerns about ideas being stolen (Ankrah et al., 2013)
	Lack of incentive/reward system within university (Siegel et al., 2003b)
	Difficulty finding companies with appropriate profile (Salter, 2009)
Cultural	High personnel turnover and lack of continuity in companies' research strategies (Bruneel et al., 2010)
	Lack of mutual understanding in terms of expectations, working practices and constraints (Anatan, 2009)
	Academics not fully understanding the regulatory challenges that must be met. (Litten et al., 2014)
	Compromise academic freedom (areas of research) (Ankrah et al., 2013)
	Nature of academic research isn't linked with industry interests or needs (Bruneel et al., 2010)
	"Public domain" mentality of universities (Siegel et al., 2003c)
	Short term orientation of industry research (Bruneel et al., 2010)
	University research is extremely orientated towards pure science (Bruneel et al., 2010)

Table 1.9 Comparison of Academic and Industrial Research and Development

Factor	Academia	Industry
Purpose	To advance knowledge of the physical world.	To advance company business against competition.
Choice of Topics	Chaining based on experience.	Match between company needs, market trends and individual experience.
Predominant Expertise	Phenomena and techniques.	Products and processes of interest to the company.
Approach	Completeness is important. (I.e. seeks most complete response to research question)	Timeliness often more important than completeness. (I.e. seeks fastest route to answer)
Publication of results	Usual and important	Only if not important to competitors
Highly valued	Advance of field of research Intrinsic virtues of work	Impact on business

Adapted from (Konecny et al., 1995)

Table 1.10 'Common ground' between academia and industry

University	Common	Industry
Public mission	Creating value for society	Shareholder value
Publications	Reputation	Revenue
Project research	Research	Practical research
Theoretical drivers	Science driven	Results driven
Shared resources	Competitiveness	Private resources
Sharing results	Value	Retain results
Creating knowledge	Sharing knowledge	Capturing knowledge
Open source	Collaborative innovation	Private source
Investigator needs	Patient needs	Market needs
Education	Exchange know-how	Retain know-how

From Ivascu *et al* (Ivascu et al., 2016)

1.2.3 Summary

Collaboration between industry and academia has been studied for decades from the perspectives of scientists, engineers, business analysts, management scientists and government agencies (Culliton, 1983, Markman and Siegel, 2008, Witty, 2013). The literature has gathered a critical mass to the point that a new field – the subject of collaboration science - has been proposed (Papadaki and Hirsch, 2013). This scoping review has enabled the following responses to the guiding questions, outlined in Section 1.2:

How do academia and industry currently interact in translational medicine and what forms do these collaborations take?

Literature describing collaboration between academia and industry specific to translational medicine is rare, with the majority of the literature focusing on collaboration in engineering fields, where such collaboration is more common (Dowling, 2015). However, it is possible to gain a general understanding of how academics collaborate with industry. Collaboration is increasingly common as it becomes incorporated into a University's mission statement (Section 1.2.1). As this occurs, there is a tendency for collaborations to shift from being transactional to being more interactive, resulting in greater knowledge exchange and better outcomes from the perspectives of researchers in both academia and industry (Section 1.2.1). There are a variety of ways in which interactions between academia and industry occur, each with different characteristics in terms of degree of involvement and formalisation (Sections 1.2.2). Furthermore, it is increasingly common for academics to interact through technology transfer groups, who can 'make or break' relationships with industry depending on their negotiation stances and the support system for collaboration (Section 1.2.4).

What factors encourage or hinder of academia-industry collaboration?

The positive aspects of collaboration for academics vary from personal, to institutional, to societal (Section 1.2.3.1), with the greatest benefits tending to be experienced at an institutional level in terms of increased funding, the increased applicability of their research and exposure of students to industrial research problems (Bruneel et al., 2010). The most prominent positive aspects for industry were categorised as either inward or outward-looking according to whether the companies builds on its own capabilities, or whether the result it improved perception or influence. Of these, the most commonly discussed were access to knowledge and cutting edge research, risk and cost mitigation, the ability to recruit highly skilled workers, and enhanced image and reputation (Section 1.2.3.2).

Analysis in Section 1.2.4 shows that partners perceive numerous barriers to collaboration, which occur at the level of the collaboration process itself, barriers specific to an institutional environment, and barriers due to cultural differences. The most frequently discussed barriers in the literature at each of these levels were respectively: disagreements over IP, negative perception from colleagues, and a lack of mutual understanding of working practices. The literature review did not reveal substantial insight into the impact or frequency of these barriers. Additionally, authors emphasise that there are circumstances where the aims of academic and industry can be aligned, and highlight the need to conduct collaborations in the 'common ground' between academia and industry.

1.2.3.1 Identification of areas for further research

Much of the published literature addresses the many factors that can affect collaboration, including: the size of the collaborating company; breadth of the focus of the research

(broad versus narrow) (Kneller et al., 2014b); the nature of academic involvement (whether transactional or collaborative) (Perkmann and Walsh, 2007); the degree of formalisation; and the degree of interaction and exchange between partners. One factor that was commonly highlighted was the role subject area or department that the academic worked within as influencing collaboration (Meyer-Krahmer and Schmoch, 1998). Thus, it is reasonable to assume that the nature of collaboration in translational medicine may differ from other fields identified in the literature. Furthermore, this assertion is supported by two factors discussed briefly above: 1) the unusual importance of patents in the pharmaceutical industry, especially considering the identification of IP in other areas (Correa, 2004), 2) Negative perceptions of pharmaceutical companies and industry-funded research amongst clinicians, which may impact the formation of 'trust', a key factor in overcoming barriers to collaboration (Section 1.2.2.4). Therefore, conducting new research specific to translational medicine would support understanding of collaboration in this field, and complement the existing literature on collaboration in the engineering and physical sciences. Furthermore, while the identification and implications of numerous barriers are discussed in the literature, the significance, frequency and temporality (i.e. point in which they are encountered) of these barriers has not been assessed in translational medicine. Understanding the relative impact of pre-defined barriers on collaboration could add value by developing the literature and enabling potential solutions to be explored and prioritised

When considering which factors are the most important as a process, environmental and cultural levels, one factor that warrants future investigation stems from findings from D'Este *et al.* which highlight the strongest predicting feature of future collaboration among academics as past experience of working with industry. Academics who have collaborated previously are more likely to collaborate more frequently and have a greater variety of interactions with industry (D'Este and Patel, 2007). The summation of this is that some academics show a predisposition to interact repeatedly with industry over

time, and that their experiences also encourage investment in further collaboration. Thus, identifying the characteristics of these individuals and the environments they work within could provide insight into the relative importance of individual, environmental and cultural factors, and determine where future efforts should be placed. The implications of this would determine whether the ‘super collaborators’ need to be recruited, ‘made’ (e.g. through tailored PhD programs), or whether environmental changes can encourage collaboration. Furthermore, additional information on the origins of collaborations would enable the design of a university ecosystem to support and facilitate such academics. Information on how initial contact between the groups occurs and develops, as well as identification of the stage of research development in which resources are invested by both parties, would add to the knowledge base. This is especially true for understanding the reasons underlying early stage research, where the likelihood of research being commercialised is relatively low.

Additionally, while acknowledging the importance of TTOs and university bureaucracy, most existing research focuses on industrial or academic researchers’ experience of collaboration. This neglects the potentially critical roles played by other university stakeholders, such as administrative staff and TTOs, that facilitate or oversee many of the processes identified as either helping or hindering potential collaborations (Section 1.2.4). For example, disagreements over IP are generally between the company and the TTO, rather than individual PIs in academia and industry.

1.3 Theoretical frameworks

A theoretical framework is a logically structured representation of the concepts, variables and relationships involved in a scientific study, with the purpose of clearly identifying what will be explored, examined, measured or described (Silverman, 2010). Literature in the area of university-industry relationships is currently pre-paradigmatic, meaning there is no standard theoretical framework for analysing collaborations in this area (Rothaermel et al., 2007). When considering collaborations generally, researchers have employed theories from different fields in order to analyse and make sense of the phenomenon. This creates a disparate literature on collaboration that is covered by a range of academic fields. Furthermore, existing frameworks tend to address the workings of specific collaborations, rather than the broader experiences of academics within a particular field (Bonaccorsi and Piccaluga, 1994). Since this study aims to understand the perception and experiences of collaboration for academics in translational medicine, including via the incorporation of structures such as clinical trials, this thesis aims to contribute to the literature through the generation of a novel theoretical framework. When analysing the data, a macro-meso-micro or 'levels of analysis' framework (Anderson, 1998) will be used to structure the themes and findings. The premise behind the macro-meso-micro-level framing is the idea that 'to understand the pace, direction and impact of organisational innovation and change we need to study the interconnections between meanings across different organisational levels.' The use of this framework as a basis for analysing inter-relationships is well documented (McNulty and Ferlie, 2002, Langley, 1999), and a benefit of selecting this framework over a pre-existing one is that it is flexible in allowing for the emergence of novel concepts. This research investigates the conceptualisation of academia-industry collaboration in translational medicine in terms of the culture (at the macro level), institutional environment (at the meso level) and, finally, individual academic and their characteristics and practical

experiences of collaboration (at the micro level). This framework is outlined in Figure 1.4. Initial insight from the literature review suggests that such factors are important (Sections 1.2.2 and 1.2.4), whilst allowing for the identification of new concepts specific to the field.

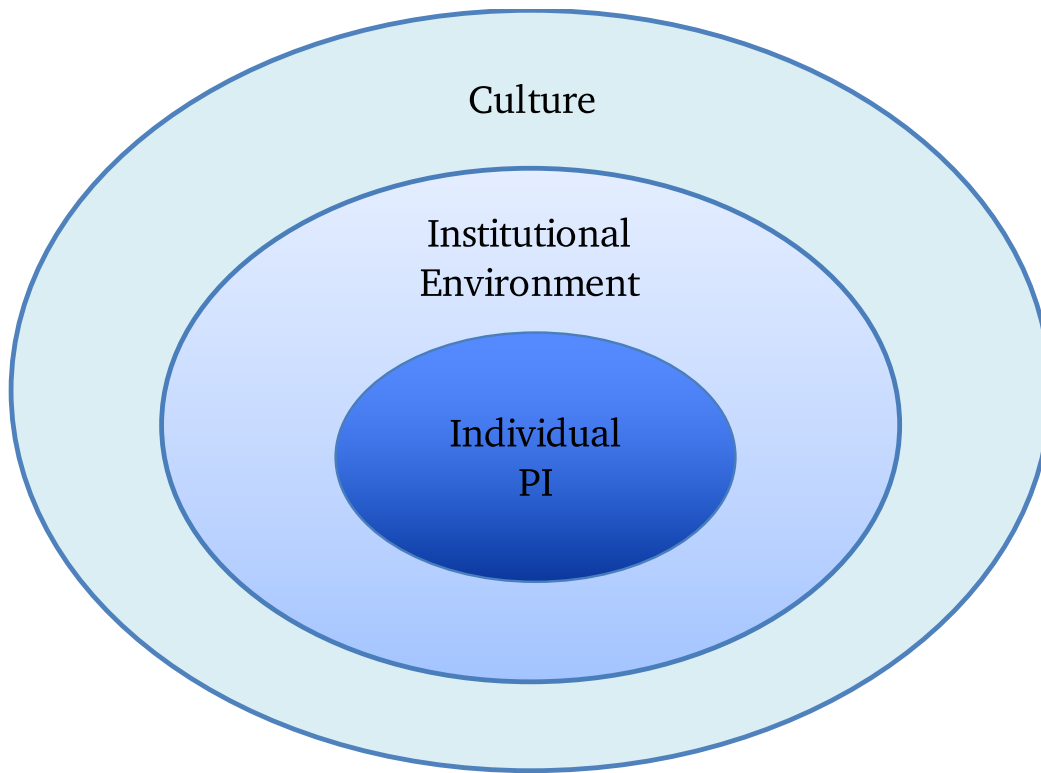


Figure 1.2 Basic structure of theoretical framework. A macro-micro-meso framework (Silverman, 2016) is being used to investigate the factors influencing academia industry collaboration in translational medicine according to culture (macro level), institutional environment (meso level) and the individual PI (micro level). The academic is depicted in the centre of the diagram as their experience is influenced by their characteristics and immediate social environment, which is in turn influenced by the broader, all-encompassing cultural context.

1.4 Research Questions

As highlighted in Section 1.2.3.1, while there is a growing literature on the benefits and drawbacks of academia-industry collaboration generally, there is little published literature specific to the field of translational medicine. This is an area with its own specific challenges, as highlighted in section 1.1.1, and in order to increase understanding of this area, among others, this thesis proceeds to answer the following research questions:

1. What is the current landscape of academia-industry collaboration in translational medicine?
2. What are the key barriers to collaboration in translational medicine, and to what extent do they impact the progress of collaborations?
3. What managerial and/or organisational strategies could be implemented to maximise industry-academia research collaboration?

The responses to these research questions would develop the existing literature by providing a novel insight into how collaboration operates within this field, in terms of the practical, institutional-environmental and cultural factors affecting collaboration.

1.5 Outline of Chapters

This thesis considers the role of academia-industry collaboration in translational medicine, with a focus on understanding how collaboration is currently experienced by academics in terms of the forms it takes and the factors that affect it both positively and negatively. Following on from the scoping review of the literature (Section 1.2) and formulation of the research questions to be investigated (Section 1.4), the research design is outlined and justified, and a description of the methodology provided (Chapter 2). In Chapter 3, the first of the results chapters, a questionnaire is administered to Principal Investigators within the University of Oxford who have collaborated with industry to provide an insight into the current landscape for collaboration in translational medicine. The insights gained here are then further developed in Chapter 4, through a process of semi-structured interviews with 26 Principal Investigators. In the final results chapter, Chapter 5, interviews with facilitating groups within the University (that is to say the groups responsible for contracts, technology transfer and commercialisation) are described, and the feasibility of strategies to improve collaboration are evaluated. The findings from the three results chapters are then analysed in the context of the literature and the original research aims in Chapter 6, the discussion. This final chapter also considers the methodological choices, further areas for potential research and implications for both university and government policy. The structure is summarised in Figure 1.3.

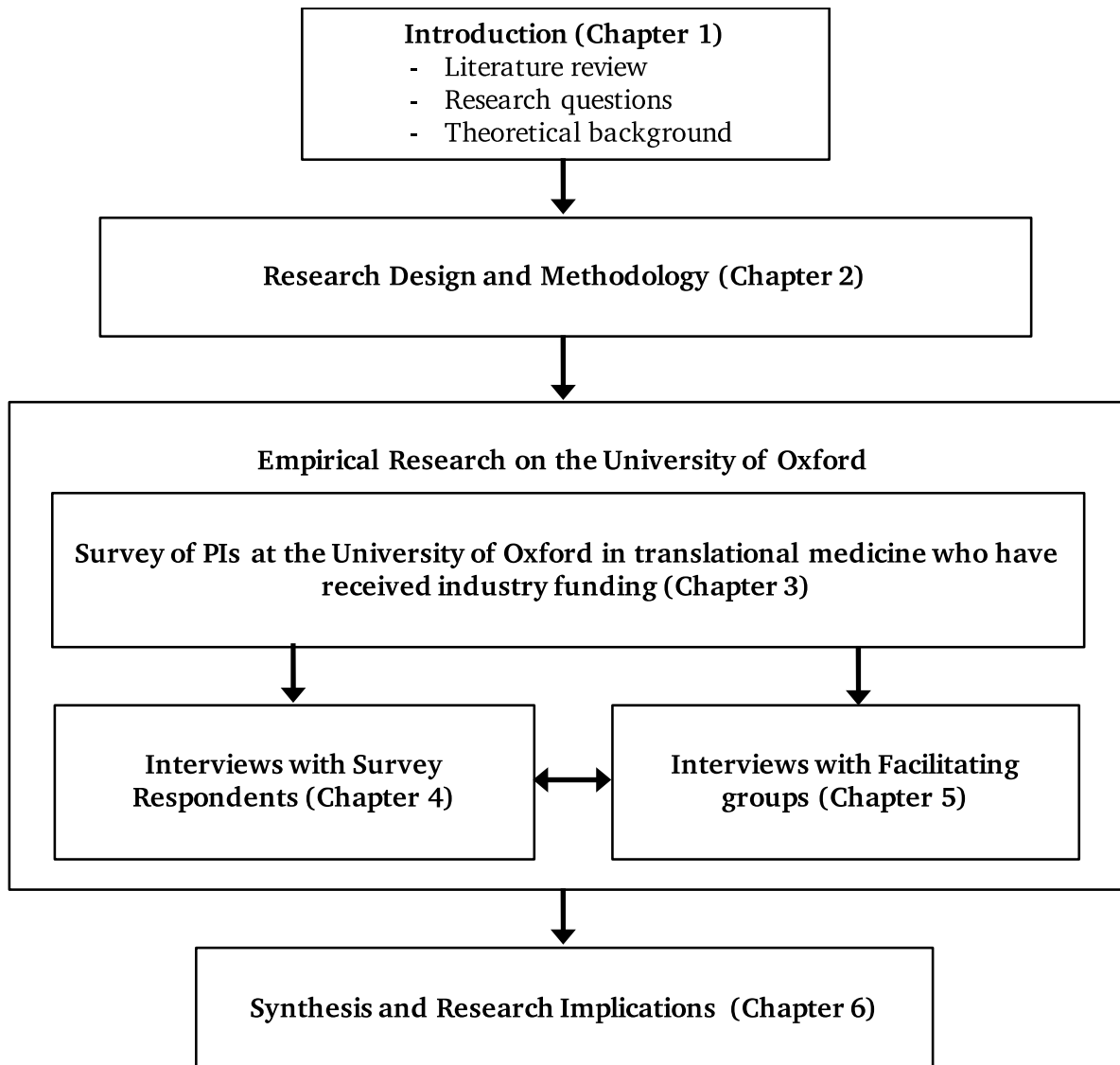


Figure 1.3 Overview of thesis structure

Chapter 2: Methodology

2.1 Introduction and Research Design

This research aims to develop a better understanding of academia-industry collaboration in translational medicine, from the perspective of researchers and staff at the University of Oxford. As discussed in Section 1.5, this research addresses the following overarching research questions:

1. What is the current landscape of academia-industry collaboration in translational medicine at the University of Oxford? (Chapter 3)
2. What are the key barriers to collaboration in translational medicine, and to what extent do they impact the progress of collaboration? (Chapters 3 and 4)
3. What managerial and/or organisational strategies could be implemented to maximise industry-academia research collaboration? (Chapters 4 and 5)

In order to answer these questions, a study with a multi-stage, sequential research design was used, comprising three stages in total, each with its own set of 'study questions'. A mixed-methods approach was used to enable more flexibility towards data collection, and increase the validity and reliability of results in comparison with the use of one method alone (Hennink et al., 2010). In the first stage of this study, a questionnaire was used to gain an insight into the 'landscape' of academia-industry collaboration in translational medicine, in terms of the characteristics of PIs involved in collaboration and the nature of their research (research question 1). This exploratory portion sought to collect a breadth of information about a context in which collaboration has not previously been investigated, and to gain initial insight into the similarities and differences between collaboration in translational research as opposed to other fields addressed in the

literature. In addition to information on the 'landscape' of collaboration, the results of this first stage (outlined in Chapter 3) provided an insight into which barriers academics perceived as most important (research question 2). However, further detail was needed to determine the frequency and impact of these barriers.

During the second stage, a series of semi-structured interviews were conducted with PIs who had collaborated with industry (Chapter 4). These interviews built on the findings from the first stage - in particular the identification of the most impactful barriers (research question 2) - and added a depth of information not possible to obtain via the questionnaire. In this stage the potential efficacy of strategies to improve industrial collaboration was also investigated (research question 3). However, the data obtained from the PIs, whilst significant, provided only a partial view on the feasibility of implementing such strategies. Therefore, a final stage of data collection was undertaken.

In the third and final stage of this study, a series of semi-structured interviews was conducted with three facilitating groups within the University of Oxford: Research Services (RS), Oxford University Innovation (OUI), and Business Development (BD) (Chapter 5). These groups are respectively responsible for contracting, intellectual property (IP), and forming relationships with industry. Their perspectives informed the feasibility and utility of implementing new strategies to improve collaboration (research question 3).

The results of each of these three sequential stages were considered cumulatively to inform both the development of a novel theoretical framework, and the design and focus of the subsequent research stages. This research comprises a mixed methods, cross-sectional study that examines the experiences of collaborating academics and facilitating staff at the University of Oxford within a post-positivist paradigm (as explained in Section 2.2). This research design was advantageous as it allowed an exploratory investigation into a novel field of research, providing both breadth and depth, whilst allowing the

emergence of practical recommendations to improve collaboration. This research does not evaluate the performance of individual collaborations, but rather considers the collective experience of academics collaborating with industry in translational medicine.

2.2 Methodology and Philosophical Approach

This research is informed by a critical realist ontology¹ and epistemology² within a post-positivist paradigm. Positivism is the basis of most research in the natural sciences, which assumes that the world exists and is knowable as it really is (Cohen et al., 2000). It aims to establish cause and effect through observation, measurement and experimentation as a way to objectively explain phenomena (Trochim and Donnelly, 2001). Post-positivism differs from this by recognising that observations are fallible and that people are inherently biased by their cultural experiences and perceptions. Within this post-positivist paradigm, a critical realist ontological perspective supports the idea that while there is a 'truth', this will be construed by different people in different ways, and thus cannot be perfectly understood (Walliman, 2006, Guba and Lincoln, 1994). As a result of this, post-positivism lends itself to qualitative research methods as a way to consider multiple perspectives of an experience and identify meaningful relationships (as opposed to a quantitative or experimental methodology which pertain more to positivist paradigms) (Walliman, 2006). Additionally, because of the fallibility of measurement and the influence of internal biases, a post-positivist paradigm emphasises the need for the use of multiple measures and observations – triangulation of methods – as a way to overcome the error and bias present within each method (Trochim and Donnelly, 2001). This is particularly relevant when dealing with attitudes and perceptions, as in this study.

¹ Ontology refers to the “philosophical assumptions about the nature of reality”

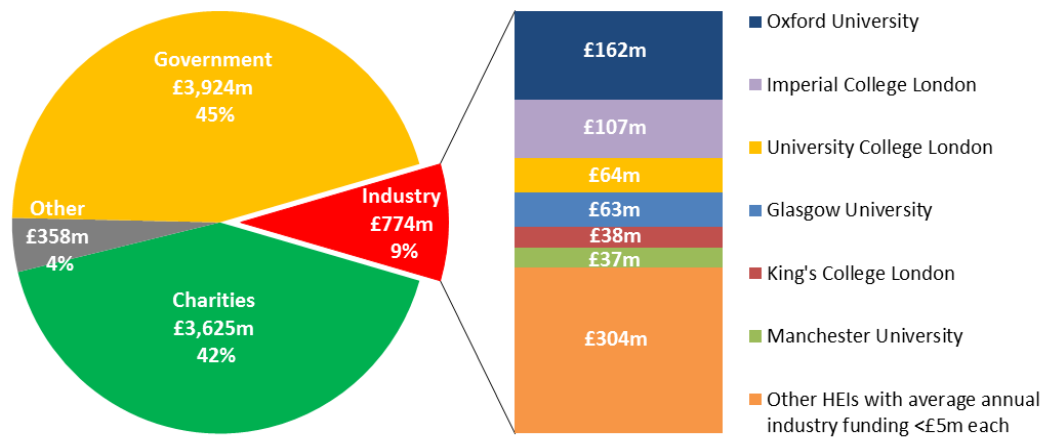
² Epistemology refers to the “general set of assumptions about the best ways of inquiring into the nature of world”

EASTERBY-SMITH, M., THORPE, R. & JACKSON, P. R. 2008. *Management Research*, SAGE. (pg 61)

2.2.1 Research Setting

The University of Oxford was selected as an initial site of analysis for several reasons. Firstly, due to its high proportion of industry funding for translational research. In the seven years for which complete information on industry funding for all UK universities is publicly available from the Higher Education Statistics Agency (2007/08 – 2013/14), the University of Oxford has attracted over 20% of all industry funding in the medical sciences, more than any other UK university (Figure 2.1). Secondly, due to the breadth and quality of the research. Research within the Medical Sciences Division (MSD) and Mathematics, Physics and Life Sciences Division (MPLS) spans the biomedical research translation continuum from basic science discovery to clinical practice and public health impact (Drolet and Lorenzi, 2011). The University of Oxford is considered amongst the leading biomedical research institutions in the world, and has been ranked first for clinical, pre-clinical and health sciences by the Times Higher Education World University Rankings for the last four years (2012-2015) (THE, 2015), and in 2016 was the first university outside of the US to be ranked first globally (THE, 2016)

Furthermore, as a research student at the University of Oxford, the author was afforded access to a range of academics and university administration staff that would not have been possible otherwise. On this basis, the University of Oxford Medical Sciences Division affords an attractive setting to examine university-industry collaboration in translational medicine.



Source: Higher Education Statistics Agency, 2014

Figure 2.1 UK Higher Education Institutions (HEIs) research income from industry in medical sciences. Medical sciences encompasses Higher Education Statistics Agency (HESA) subject categories of clinical medicine, anatomy and physiology, and pharmacy and pharmacology. Data represent a six-year aggregate from 2007/08-2013/14 (source: HESA, data available upon registration)

2.2.2 Research Participants

This study investigated experiences of academia-industry collaboration from the perspective of the university, for both theoretical and pragmatic reasons. This research considers the experiences of individuals who have chosen to collaborate with an external group in their research. Thus, from a theoretical perspective, academics are an attractive group to study due to their relatively high levels of autonomy which allows them to engage in discretionary behaviour (Aghion et al., 2008). Examining this same activity in an industrial setting is less attractive since employees have much lower levels of autonomy than in an academic setting. Furthermore, in addition to the reality of academic experiences of collaboration, understanding academics' perceptions of their experiences are crucial, as these underlie their willingness to participate in collaboration. Indeed, as academics operate with a high level of autonomy within a professional bureaucracy, their willingness to participate is fundamental to the continuation of university-industry knowledge transfer. Similarly, by understanding academics' views of the negative aspects of engagement, it is possible to gain insights into the nature and drivers of university-industry collaboration.

From a practical perspective, data on academic activities are more readily available than those on private companies, and academics themselves were a more accessible data source than industry employees, particularly because industry decisions tend to be attributed to the firm rather than a specific employee, and so identifying appropriate participants in industry would have been challenging. It is also possible that academics would be able to be more open during interviews than industrial employees who may be bound by company policies of confidentiality.

2.3 Methods

This section outlines the specific way in which this methodology will be applied to answer the research questions (Section 2.1).

2.3.1 Survey of Principal Investigators at the University of Oxford

The first research stage aimed to explore the experiences of academics within the University of Oxford who have collaborated with industry in translational medicine. This study employed a cross-sectional online questionnaire comprising both quantitative (fixed) questions and qualitative (open-ended) questions. Questionnaires are widely used for data collection in the social sciences, since in comparison with other types of survey, they are a quick and inexpensive data collection method and, due to the privacy and confidentiality afforded the participant, often encourage more candid and honest responses (Bryman, 1989). However, questionnaires, particularly in the online format, tend to have a low response rate (varying between approximately 20-40% (Kulej, 2007, Bryman and Bell, 2015)), and the lack of interaction between the participant and the researcher can result in the loss of detail and discrepancies between the intentions of respondents and the way the data are interpreted (Walliman, 2006).

In this study, a questionnaire was chosen in order to gain a broad, general insight into the landscape of collaboration in translational medicine, and for the speed of available results. Furthermore, concepts from the literature were used to understand how academia-industry collaboration is experienced in translational medicine in comparison to other fields, and to identify areas for further exploration in subsequent research stages.

2.3.1.1 Study population

The study population comprised Principal Investigators (PIs) from the University of Oxford with confirmed experience of success in attracting funding from industry for translational research over seven years (2007/08–2013/14). This period was chosen as 2007/8 was when the Higher Education Statistics Agency (HESA) began collecting data on industry funding in UK universities, and allowed for a greater range of collaboration experiences to be recalled. While studies with a shorter recall period (up to three months) are generally found to be more reliable for self-reported data (Steptoe et al., 2010), a longer recall period is justified in this case as industrial collaboration is expected to constitute a rare behaviour, thus is less likely to have occurred over a shorter recall period, and is more likely to be salient in the mind of the participant (Steptoe et al., 2010). PIs who have successfully obtained research funding from industry were selected for investigation due to their experience with industry and because they represent a more easily accessible population than academics who had collaborated with industry without receiving industry funding, for which records are incomplete.

Academics who had received industry funding at the University of Oxford during the period of October 2007 to November 2014 were identified using administrative databases courtesy of University Research Services. The database comprised entries for all industry funds awarded to PIs within the University over the specified period. This list of funding awards was filtered using categories outlined by the Higher Education Statistics Agency (HESA) as relating to Clinical Medicine (HESA Subject Code A3), Anatomy and Physiology, Pharmacy and Pharmacology (HESA Subject Codes B1, B2, and B3, respectively), and Biological sciences where the research relates directly to humans i.e. Zoology and Botany do not meet inclusion criteria (HESA Subject Codes C1, C4, C5, C6,

C7, C8, C9, CZ were included³). This filter ensured that the respondents received industry funding for research in relevant areas of translational medicine, and also enables results generated here to be compared and interpreted in relation to similar studies conducted at other universities.

Each funding award in the list was individually checked to confirm its eligibility on the basis of the inclusion criteria as defined in Table 2.1. Participants were included in the study if they: a) were PIs, b) had received at least one industry grant or contract for biomedical research directly related to humans in 2007/08–2013/14, and c) were on the payroll of the University of Oxford when the study was conducted (enabling contact via a university email address and within the remit of the ethics approval given for this study). Participants were excluded if they were not PIs, had not received industry funding for biomedical research directly related to humans (e.g. Zoology or Plant Sciences), had not received industry funding during the period 2007/08 to 2013/14, or were no longer at Oxford.

After removing duplicates, erroneous submissions, and those PIs who were no longer at Oxford, the survey was administered to a total of 229 PIs. A total of 14 PIs subsequently indicated that they were ineligible to participate, either because they had been misidentified as a PI or because they had not received industry funding. Therefore, the final eligible survey population comprised 215 PIs. For this study sampling techniques were not required as access was available to the entire study population.

³ Full descriptions of HESA subject categories and definitions are available at <https://hesa.ac.uk/component/content/article/44-statistics/information-provision/102-bespoke-data-service-other-information?limit=1&start=3> (access date 08/09/2013)

Table 2.1 Inclusion/exclusion criteria for Survey of Principal Investigators at the University of Oxford.

Inclusion Criteria	Exclusion Criteria
- Principal Investigator (PI) on payroll at the University of Oxford - Has received at least one industry grant for biomedical research directly related to humans since 2007/08. Or - Has received industry funding within HESA defined categories: - Clinical Medicine - Anatomy and Physiology - Pharmacy and Pharmacology - Biosciences where the research relates directly to humans (i.e. Zoology and Plant sciences do not meet inclusion criteria)	- No longer at University of Oxford - Has not received industry funding - Has received industry funding for research, but not directly related to humans Or - Industry funding for research not within HESA specified categories.

HESA, the Higher Education Statistics Agency

2.3.1.2 Questionnaire development and administration

The survey instrument was developed based on the research questions and informed by a scoping review of the relevant literature (Chapter 1). To ensure that this study contributes to the existing body of literature, concepts and tools from previous research studies were used, specifically two typologies; one for the different types of academia-industry interaction (Chin-Dusting et al., 2005) , and one for the different stages of translational development (Waldman and Terzic, 2010b). In order to assess the reliability (i.e. consistency of responses) and face validity (i.e. the accuracy of the features measured) (Bailey, 2008) of the survey instrument and check time-to-completion, 14 professional colleagues were asked to complete and comment on a pilot version of the survey prior to launch, and the phrasing of questions and question formats used in the survey was adjusted according to their feedback. After incorporating feedback and testing the questionnaire with two further colleagues, the final survey instrument was launched. The structure of the questionnaire is outlined in Section 2.3.1.3, and a full copy of the survey is included in Appendix ii. In order to maximise the survey response rate, the questionnaire was sent out via a personalised email from a credible and well-known University contact with three, subsequent, weekly reminders. It was administered during November-December 2014, and responses were collected using the online questionnaire provider Survey Monkey (www.surveymonkey.com). The Central University Research Ethics Committee (CUREC) at the University of Oxford approved this study prior to commencement. Full details of this approval can be found using reference SSD/CUREC1A/14-220 (See appendix i).

2.3.1.3 Questionnaire structure

The final survey instrument comprised a participant information sheet (appendix iii), six substantive questions, one question regarding informed consent, and four questions regarding demographics. Respondents were asked to base their responses on their experiences of industry funding during the period 2007/08 to 2013/14. The six substantive questions addressed the following areas:

1. Motivation for entering into collaboration with industry

This open-ended question included a comment box and allowed the academic to write freely about their motivations for interacting with industry.

2. Types of collaboration with industry

The frequency of different types of university-industry collaboration was measured quantitatively using a six-fold typology as defined by Chin-Dusting et al. (2005). Participants were asked to distribute 100 points to represent how the total amount of industry funding that they have received was distributed across six different types of collaboration as shown in Table 2.2 (a).

3. Phases of translational research

The phase of translational research was measured quantitatively using a six-phase continuum of clinical and translational science (Waldman and Terzic, 2010b). This was used as an alternative to the clinical trial phases (i.e. phase I, II or III) to encompass a broader range of translation and ensure a more consistent understanding for clinical and non-clinical PIs. Participants were asked to distribute 100 points, representing the total

amount of funding they received, across six phases ranging from T0 to T5. Definitions for these phases as presented in the survey are shown in Table 2.2 (b).

4. Advantages and disadvantages of industry funding

The advantages and disadvantages of industry funding in comparison with funding from Research Councils and charities were collected through two comment boxes. These questions were left open-ended as although some advantages and disadvantages to collaboration have been identified in the literature, these are not particular to translational research. This section was also used as a repeated measure for earlier topics: advantages were analysed in conjunction with the ‘motivations’ to cross-validate positive aspects of collaboration, and disadvantages were analysed in conjunction with ‘barriers’ to cross-validate negative aspects of collaboration (Littell et al., 1998).

Table 2.2 (a) Types and (b) stages of translational research.

(a)

Types of Relationships
Consultations and fee for service, including contract research outsourcing
Competitive grants sponsored by industry
Industrial sponsorship of training and education programs
Industrial sponsorship of investigator-led research
Institute–institute liaisons.
Partnerships between academia, industry and the government

Typology of academia-industry relationships as defined by Chin-Dusting et al. (Chin-Dusting et al., 2005)

(b)

Stage	Research concerns
T0	Identification of targets, biomarkers, genes, pathways, mechanisms
T1	First in human studies, Phase I-II trials, proof of concept
T2	Phase III trials, clinical efficacy, clinical guidelines
T3	Dissemination, community engagement, health services research, comparative effectiveness
T4	Public health, prevention, population health impact, behavioural modifications, lifestyle modifications
T5	Social health care, political security, economic opportunity, access to education, access to health care

Stages as defined by Waldman and Terzic (Waldman and Terzic, 2010b).

5. Barriers to collaboration with industry

The barriers to collaboration with industry were measured both quantitatively using a 17-fold typology, as explained below, and qualitatively using an open-ended question and interviews. The typology was formulated by listing the barriers identified in the scoping review to encompass aspects emergent from the literature as wholly as possible. This initial list was then reviewed, refined, and validated by professional colleagues during the piloting process, to compile the final list as presented in the Survey (appendix ii). Participants were asked to assess 17 barriers using a five-point Likert rating scale, from 'strongly disagree' to 'strongly agree'. An open-ended 'other' box was also included to allow for any barriers not identified in the typology. A typology of barriers does not allow for as much flexibility in responses as open-ended questions, however it was selected for use in this question as responses to open-ended questions tend to be shorter (i.e. only listing one or two barriers) and response rates tend to be lower than for multiple choice questions (Bailey, 2008). As barriers are a key aspect for exploration, a multiple choice response option (as opposed to an open-ended response) is more appropriate as this should ensure a higher response rate and provide additional stimulus for the academics when completing the final section, while still allowing emergent barriers to be captured by providing an 'other' comment box.

6. Strategies to improve collaboration with industry

This section comprised two questions which encompassed both quantitative and qualitative aspects. In the first part of this section respondents were asked a binary yes/no question as to whether they believed that the University should seek to increase industrial funding in academic translational research. The second part of this question comprised an open-ended response box asking for an explanation of their first answer, and if the response was 'yes', then the suggestion of potential strategies that the university

could employ to improve collaboration with industry was also requested. A full copy of the survey is included in Appendix ii.

2.3.1.4 Analysis

Of the total survey population of 215 PIs, a total of 169 PIs completed responses to the survey in the month following the launch, constituting a response rate of 79%. Prior to analysis, the data collected from all 169 responses were aggregated and compiled for each individual question. Responses to open-ended questions on Motivations, Advantages, Disadvantages and Strategies generated qualitative data that were manually coded and analysed independently by two researchers: the author and Dr. Pavel Ovseiko (University of Oxford). Emerging themes were developed and refined inductively using a grounded-theory type approach with nil prior assumptions, and any disagreements over the interpretation and synthesis of the data were resolved by consensus. Eight themes were identified for motivations, nine for advantages and seven for disadvantages. Themes, definitions and example quotes are provided in context in Chapter 3. Once a final coding framework was determined all responses were recoded to fit this by the author. Frequency data illustrating how often each theme occurred were used to supplement the qualitative analysis provided (Hannah and Lautsch, 2010). Responses to closed-ended questions on Types, Phase and Demographics generated quantitative data which were analysed within Excel (Microsoft 2016 Version 15.20). Missing data were not substituted for.

2.3.2 Interviews of Principal Investigators at the University of Oxford

The aim of the second research stage was to understand the impact of barriers on academics' experiences of industrial collaboration with respect to both frequency and severity. Additionally, further delineation of some of the cultural, environmental and process factors affecting industrial collaboration was sought.

Qualitative methods were chosen for this stage of the study as they enable the exploration of complex questions about human experiences (Creswell, 2007). Semi-structured interviews can be particularly informative as they enable the respondent to discuss ideas in their own words (Rubin and Rubin, 2012), and ensure that the interview is focused while allowing for rich data collection, including data from areas outside the topic guide (Patton, 2002).

2.3.2.1 Topic guide development and pilots

Questions were written to align with good practice as recommended by Berg and Rubin and Rubin (Berg, 2004, Rubin and Rubin, 2012). This included essential questions covering the topic of interest; similar but differently worded questions to check reliability; 'throw-away' questions to build rapport and pace the interview, and probes to encourage elaboration and draw out details.

Interview questions were informed by both the literature and preliminary survey results. The guide was piloted with six academics with experience of industrial collaboration to ensure that topics were clear, likely to be comprehensible to participants, and likely to yield useful data. The topic guide was then revised after some initial interviews to incorporate additional topics that had arisen, for example, the impact of long-term

relationships with industry on collaboration. The interview guide comprised four key sections:

1: Introduction and background information

The initial portion of the interview introduced the participant to the study and asked basic background and demographic questions. The reasons for this were two-fold: firstly, this information could be used and cross-checked with findings from the survey, and secondly to ease the participant into the interview and establish a rapport (Rubin and Rubin, 2012).

2: Experience of Collaboration

This section explored the participant's experience of collaboration with industry, including the role that industry had played in their research. This section encompassed three main aims: a) to understand the participant's perspective and the context of their research and collaborations when discussing barriers and strategies, b) to assess their perception of the role of industry in translational medicine and c) to learn more about the role of long-term relationships with industry in collaboration.

3: Barriers to Collaboration

In this section participants were first asked to describe any barriers they had experienced, before being shown the results from the survey as a prompt for further discussion. This section aimed to assess the impact of the barriers on collaboration in terms of both frequency and severity.

4: Strategies for Improvement

Participants were asked to suggest strategies to improve collaboration before being presented with the list of strategies identified from the questionnaire. This section aimed

to assess the perceived usefulness of the identified strategies, in addition to developing and refining more promising strategies to ensure they result in maximum benefits for the academics.

The final topic guide is provided in full in Appendix iv.

2.3.2.2 Participant recruitment and semi-structured interviews

All participants who completed the questionnaire outlined in Section 2.2.1 were invited to volunteer for interview by submitting their email address in a linked online form. Consequently, all respondents met criteria for inclusion as outlined in Table 2.2. This form was recorded separately from the survey data in order to preserve the anonymity of responses. Of 169 questionnaire respondents, 38 agreed to be contacted for interview, and all submitted email addresses were contacted to make further arrangements, with initial communication occurring in the weeks following the survey. If no response was received, PIs were emailed up to two prompts, sent one and two weeks following the initial request for interview. A total of 26 interviews were conducted with Principal Investigators between February and June 2015. Interviews were not conducted if a suitable time could not be arranged in the time frame, if no response was received from the PI following two prompting emails, or if the PI decided to withdraw from the study. An additional interview was conducted with one PI, whose data have not been used in this analysis as the participant declined audio recording during the interview. Interviews were conducted face-to-face in the academic's office or meeting room, and all recorded with permission. A topic guide of 30-45 minutes was used, but interview length varied from 20-90 minutes dependent on participant's availability and the level of detail provided in responses. Interviews were all undertaken by the same researcher (the author, Natasha Davie) to increase consistency.

2.3.2.3 Analysis

All interviews were transcribed verbatim by either the author or a professional transcription service. After transcription all identifiable information (such as names of researchers, names of companies, specific details of collaborations etc.) was redacted from the transcripts to ensure anonymity.

Framework analysis was used to code the interview transcripts and summarise the data. This method is particularly suited for interview data, and enables the reduction of large quantities of data whilst maintaining a strong link with the original data, thus retaining context throughout the iterative analysis process (Srivastava and Thomson, 2009, Gale et al., 2013).

In this study the data were first reviewed by the researcher in order to become familiar with the whole dataset. Initial impressions were noted in a separate document (e.g. where a participant had expressed particularly strong or contrasting views to their colleagues). Three transcripts were then selected for initial analysis. During the initial coding round open codes were used to inductively analyse the data and allow for the emergence of new concepts (Silverman, 2010). These codes were repeatedly compared and evaluated for accuracy and comprehensiveness by the researcher. Open codes were relevant to answering the research questions. For example, if the purpose was to describe the peer-related social environment of academia, the open codes had to describe the behaviour and activities of peers and the relationships with peers that supported or hindered collaboration. Codes referred to specific incidents (e.g. the origins and consequences of collaboration), groups (e.g. Research Services, Oxford University Innovation), processes (E.g. contracting), perceptions (e.g. the importance of collaboration), structures (e.g. intellectual property, overheads) and individual barriers and strategies.

Once these three transcripts had been coded, they were read by another researcher (Dr. Pavel Ovseiko, University of Oxford) and the reason(s) why each code was interpreted as meaningful were discussed, as well as how it might be useful in answering the research questions. After discussion a new set of codes was agreed upon and defined, and used to form the analytical framework. This analytical framework was applied to the rest of the transcripts, and continually refined during the coding process to incorporate new codes or group conceptually similar themes together. A final analytical framework was then applied to all transcripts using the software program NVivo Version 11.0.0 (QSR International, Cambridge, MA). Once all the data had been coded, a matrix was constructed in Microsoft Excel Version 15.25 (Microsoft, Redmond, WA) where each column comprised one code and each row comprised one participant. The data were then summarised for each code and participant using verbatim words where possible and inserted into the relevant cell in the matrix. Themes were then generated from the dataset by reviewing this matrix and identifying links between and within categories and participants. This process was influenced both by the original research objectives and by new concepts generated inductively from the data. Themes were considered more important if they were mentioned with a high frequency (see Section 2.3.2.4), or if they were seen as particularly important by the interviewee. The validity of a theme was evaluated by comparing data within and between codes, and subsequently by rereading the entire dataset with respect to these themes. Themes identified were subsequently placed within concepts in the conceptual framework deduced in Section 3.3.2. During the interpretation stage, analysis attempted to go beyond descriptions of individual cases towards developing synoptic themes which offered possible explanations for what was happening within the data. Ideas were generated, explored and fleshed out through constant comparison and discussions with academic supervisors and colleagues.

2.3.2.4 Reporting of results

In reporting the results of a thesis, it is first important to define the concepts used to ensure consistent interpretations across readers. Much of the research in this thesis aims to address barriers to collaboration. In this context 'barriers' means any factor negatively affecting collaboration for the academic, including those encountered during the collaboration, as well as factors preventing the collaboration from occurring in the first place. Thus, barriers can be taken to mean 'barriers to the successful initiation, continuation or completion of a collaboration, or factors that result in negative experiences from academics'.

Another key concept requiring explicit definition is the way in which the comments from academics are presented in the discussion of interviews and responses to open ended questions. Exact numbers of PIs discussing topics are rarely reported in the text, as the number of PIs discussing a specific factor is not necessarily indicative of the importance or impact of that factor (Hannah and Lautsch, 2010). Furthermore, a topic raised in only one interview can sometimes be of key interest as a divergent case (Eisenhardt, 1989). Therefore, where a concept has been mentioned by more than one academic, the following terms are used to broadly reflect the following:

'a few' (0-19% of all participants in that stage)

'some' (20-39%)

'several' or 'many' (40-59%)

'most' (60-79%)

'the majority' (80-99%)

'all' (100%).

2.3.3 Interviews with facilitating groups at the University of Oxford

Through the survey and interviews with Principal Investigators at the University of Oxford, three facilitating groups within the University were identified as important in supporting collaboration between academia and industry in translational research (see Chapters 4 and 5). These groups were Research Services (RS), Oxford University Innovation (OUI, formerly Isis Innovation), and Business Development (BD), responsible for contracts, technology transfer, and commercialisation, respectively (Division, 2015). One aim of this study was to understand the constraints that these groups work within and to evaluate the potential for the implementation of strategies to improve collaboration. In evaluating both the constraints and strategies, semi-structured interviews were used for those reasons outlined in Section 2.3.3, and additional follow-up interviews and meeting attendance with Research Services department enabled clarification of findings and greater insight into the constraints of this particular group.

2.3.3.1 Semi-structured Interviews

In total, 23 semi-structured interviews were conducted with 17 individuals, using a separate topic guide for each group, informed by previous research stages and in the case of OUI, existing literature on Technology Transfer Offices (see appendices vii, viii and ix for topic guides). Interviewees were selected by talking to the head of respective groups and determining who had appropriate experience, and then by access. Interviews took place at the groups' respective offices, and in some cases access was restricted by time constraints and gatekeepers (Seidman, 2013). Within Research Services semi-structured interviews were conducted with four team members, with two members being interviewed twice, making six recorded interviews in total. In seeking clarification for the ideas emergent from these interviews, a further four members of RS were contacted

informally and several group meetings were attended. During the course of the interviews a schematic was developed in order to better understand the contracting process and to highlight the main 'bottlenecks' preventing progress (see Section 5.2.2.1). This schematic was subsequently refined through iterative communications with Research Services, and used to inform further interviews with team members. Upon the advice of RS, an interview with a lawyer who has worked with the university was also conducted in an informal manner.

Within Oxford University Innovations, seven interviews took place with six representatives of varying seniority. Finally, in Business Development four interviews were conducted with two representatives. In this case one participant was interviewed formally once and interviewed in an informal (without tape recording) manner on two further occasions to develop analyses. In cases of multiple interviews with the same participant, this was generally due to one of three circumstances: a) the original interview session was interrupted, b) the interview had reached the allotted time and the interviewee wished to continue the interview, or c) in the following up of interviews to develop new lines of understanding. Interviews varied in length from 30-90 minutes. All formal interviews were recorded, transcribed, and analysed in conjunction with field notes (where relevant) using the framework method in the same manner as outlined in Section 2.3.2.3.

2.4 Ethical Considerations

All studies were approved by the Central University Research Ethics Committee (CUREC) at the University of Oxford (reference number: SSD/CUREC1A/14-022).

2.4.1 Informed consent of participants

For the first research stage, respondents who accepted the invitation to take part in the questionnaire were first directed to the survey introductory page. Here, the participants were provided with information about the project, anonymity of the survey findings, an outline of what participants were required to do and how long it would take to complete the questions, an assurance that every attempt would be made to ensure the confidentiality of the data and a statement indicating that participation was voluntary and that withdrawal from the survey was possible at any stage (Appendix iii). Potential participants were asked to click on a link to confirm that they had read the participant information before proceeding. The act of clicking on this link was considered consent to participate in the study. Access to the survey was denied unless this link was clicked. For the interviews conducted in the second and third research stages, an initial statement outlining the purpose, consent, and ability to withdraw from the study was stated at the start of each interview. Additionally, a copy of the participant information sheet was presented at the start of each interview.

2.4.2 Confidentiality

No personal information (such as names, addresses, or funding amounts) was collected from participants in the survey, and all data were aggregated and anonymised for analysis. The survey was completely anonymous, and no IP addresses were stored or downloaded. As previously highlighted, when submitting an email address to be contacted for interview participants were directed to a separate online form, distinct from their submitted responses. During interviews, where names or identifiable information were collected, this information was redacted in the final transcripts. All data collected

from the relevant administrative databases are held, and were analysed, in compliance with the requirements of the UK Data Protection Act 1998.

Chapter 3: Survey of Principal Investigators at the University of Oxford

3.1 Introduction

The literature reviewed in Chapter 1 indicates that there are substantial differences in experiences of collaboration across different subjects. Thus, a lack of existing literature specific to the field of translational medicine makes it difficult to understand how experiences of collaboration in this field relates to those in other fields such as engineering. In order to answer the first research question identified in Section 1.4 of “What is the current landscape of academia-industry collaboration in translational medicine at the University of Oxford?”, a greater understanding of academic experiences of industrial collaboration in translational medicine is required. In pursuit of this, a questionnaire was administered to all Principal Investigators at the University of Oxford who were both working in translational medicine and had who were recorded as receiving industry funding since 2007/8.

The aim of the questionnaire was to answer the following research questions:

- Study question 1a) What are the characteristics of PIs in the University of Oxford receiving industry funding?
- Study question 1b) What are the barriers preventing or delaying university-industry collaboration? How do these manifest in terms of perceived disadvantages to collaboration?
- Study question 1c) What motivates PIs to collaborate with industry? Do perceived advantages support these motivations?
- Study question 1d) What strategies do academics believe would help the initiation and/or maintenance of industrial collaboration? How do these strategies address barriers to collaboration?

This chapter outlines the results of this questionnaire, beginning by outlining the demographic characteristics of the questionnaire population and respondents and proceeding to present the results of the questionnaire in the order in which the questions were asked. The results are then discussed in the context of the research questions stated above.

3.2 Results

3.2.1 Data Collection and Analysis

Academics who had received industry funding for translational research were identified using information obtained from Research Services, and evaluated for inclusion criteria as outlined in Section 2.3.1. The questionnaire was launched on 17th November 2014, and data collection was open for a further 30-day period. Two follow-up reminder emails were sent seven and 14 days after the initial invitation. The seven sections of the survey are discussed in the following sections of this chapter: Motivations (discussed in Section 3.2.3), Types of Collaboration (Section 3.2.4), Phase of Collaboration (Section 3.2.5), Advantages (section 3.2.6), Disadvantages (Section 3.2.7), Barriers (Section 3.2.8) and Strategies (Section 3.2.9). Demographic data on the respondent population were also collected (Section 3.2.2).

The final eligible survey population comprised 215 PIs, of whom 169 completed the survey, constituting a response rate of 79%. The derivation of the final list of eligible PIs is outlined in Figure 3.1. The results for responses to qualitative questions are presented as a list of the final themes, and supported by figures illustrating the frequency with which they occurred.

3.2.2 Demographics

PIs were from both the Medical Sciences Division, comprising both clinical and non-clinical researchers and the Maths, Physics and Life Sciences Division, comprising non-clinical researchers. Limited data is available on the demographics of all PIs within MPLS and MSD, however information was obtained on the birth gender and professorial titles of ‘academic’ staff within these divisions. However, instead of providing data according to the number of staff members, information was provided based on the number of Full Time Equivalents (FTE), a measure of the workload of an employee where one full time employee is equal to one FTE, and

an employee working half time is equal to 0.5 FTE and so forth. Of 7562 total staff in these divisions, 793 were classed as 'academic', comprising 767 FTEs, of which data was provided on 698.4 FTEs (Table 3.1).

Information from Research Services identified 215 currently active and employed PIs within these divisions who have received industry funding, representing 27% of academic staff. Of these, the proportion of women in the collaborating group was significantly higher than the base population (Chi² test, $p=0.0233$), representing a deviation from the trends discussed in the literature (Abramo et al., 2013). The collaborating group also comprised significantly fewer professors than the base population (Chi², $p<0.001$), indicating that collaborators in translational medicine may be less senior in the university. This may support the theory put forward by Bercovitz and Feldman (2008), that suggests that younger researchers are leading collaborations as industrial involvement is increasingly legitimised in academia.

In terms of how well the survey respondents reflect the survey population, there were slight discrepancies in the proportion of basic scientists (slightly overrepresented) and Professors (slightly underrepresented). However, overall the two populations were very similar, and a high response rate of 79% provides confidence that the collected results are generally representative of the total eligible population (Table 3.1).

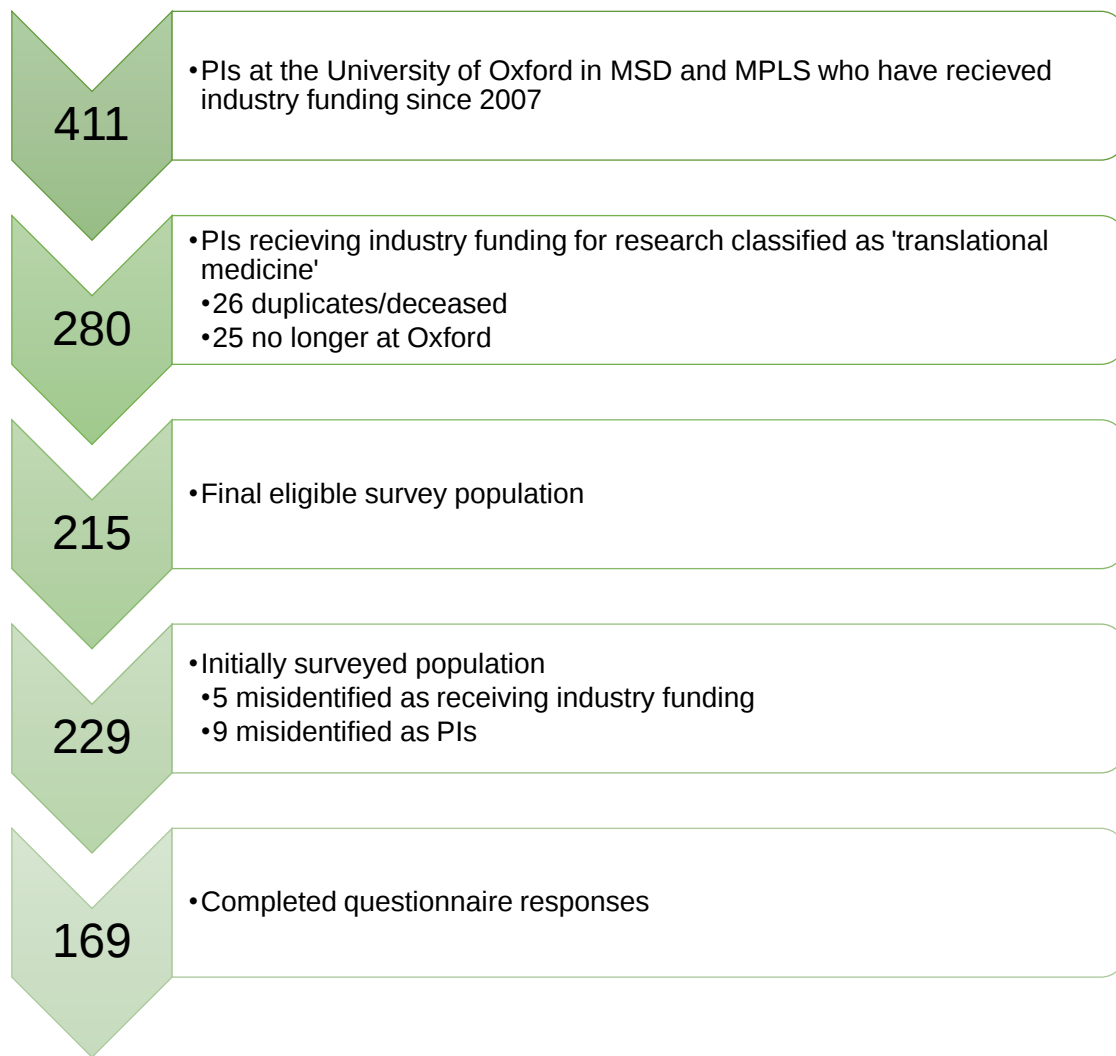


Figure 3.1 Derivation of completed responses from the initial list of PIs obtained from Research Services.

Table 3.1: Demographics for study population and survey respondents.

Characteristic	MPLS + MSD** N = 698	Study population N=215 (27% of 793)	Survey respondents N=169 (79% of 215)
Career path			
• Clinician-scientist	-	100 (47%)	76 (45%)
• Basic scientist	-	115 (53%)	93 (55%)
Professorial title			
• Yes	645(92%) ^	178 (83%)	135 (80%)
• No	53 (8%) ^	37 (17%)	34 (20%)
Gender			
• Female	115 (16%)	50 (23%)	37 (22%)
• Male	583 (84%)	165 (77%)	127 (75%)
• DNS	0 (0%)	0 (0%)	5 (3%)
Age (years)			
• ≤30	-	0 (0%)	0 (0%)
• 31-40	-	18 (8%)	14 (8%)
• 41-50	-	80 (37%)	63 (37%)
• 51-60	-	75 (35%)	61 (36%)
• >60	-	42 (20%)	31 (19%)

*Based on 2015 data from (UAS, 2015), includes data for both Research and Academic. Professors, Readers, Associate Professors and Departmental Lecturers in the University of Oxford Medical Sciences Division (MSD) and Mathematics, Physical and Life Sciences (MPLS) Division.

^Yes if listed as 'Professor', 'Reader' or 'Associate Professor'. No if listed as 'Departmental Lecturer'.

#Data presented is in Full Time Equivalent (FTE) (total FTE = 698.4)

3.2.3 Motivations

In total 161 (95%) PIs provided responses to the open-ended question “What was your main motivation for entering into collaboration with industry?”. Analysis of the responses resulted in the identification of eight parent codes, which were further refined into 17 sub-codes (see Table 3.2). In providing a general overview of the data, the frequency of these codes is also provided in Figure 3.2.

The most common motivation was ‘funding’ which was mentioned by 51% of respondents. This is consistent with the existing literature as outlined in Section 1.2.2.3.1. Funding was often mentioned alone as a key motivation, however across the dataset there was a split in the context in which it was discussed. PIs tended to discuss industrial funding in terms of its abundance and accessibility (see Table 3.2, theme 3.1 ‘Positive’), or in terms of the lack of alternative funding options (see Table 3.2, theme 3.2 ‘Negative’). Positive comments about funding indicated the availability or abundance of funding in industry, the ease of obtaining funding, or access to funds for otherwise unfunded work. Negative comments indicated a lack of, or difficulty in, procuring conventional funding, challenging interactions with funding agencies, or areas of research that Research Councils and charities were unwilling to fund (e.g. because the research topic is outside of their remit. For completeness, ‘funding’ also comprised neutral responses (Table 3.2, theme 3.3 ‘Neutral’) and responses highlighting the potential for personal financial gain (Table 3.2, theme 3.24 ‘Personal’), a motivation that has been documented elsewhere in the literature (Pronk et al., 2015). Most PIs mentioned funding in a negative sense (i.e. highlighting a lack of funding elsewhere) rather than in a positive sense (i.e. highlighting the availability of funding from industry). This indicates a potential dissatisfaction with the availability of research funding, and could mean that academics are turning to industrial funding due to a lack of other options, rather than for the genuine benefits of collaboration.

Table 3.2 Overview of themes identified in responses to the open-ended question ‘What was your main motivation for entering into collaboration with industry?’.

Code Description		Example Quotation
Theme 1: Translation		
1.1 Development and Application	Desire to see work developed and applied	(1) “Helping drive application of novel technologies developed in our lab.” (2) “Doing research that potentially has some application out there in the real world.” (3) “Hope of gaining enough ‘power’ to really translate our basic science research into clinical utility.”
1.2 Patient benefit	Desire to see work resulting in patient benefit	(1) “To commercialise research developments into treatments for patients.” (2) “To stay engaged with product development to ensure best outcomes for patients and to research.”
Theme 2: Collaboration		
2.1 Synergy	Partnering due to compatible research interests	(1) “Use the synergy with industry to address important research questions and develop new diagnostic tools.” (2) “We had common interests and it was a good way of funding certain research projects.”
2.2 Complementary skillsets	Partnering to fill gaps in resources/skills	(1) “The motivation was mutual. We have a reputation for high quality research including expertise in translational physiology and access to subjects for research. They had pharmaceutical compounds and were also to provide financial support.” (2) “Industry and academia have different capabilities. I am particularly interested in identifying and optimizing... novel potential drug targets. Industrial collaboration is accelerating this process.”
Theme 3: Funding		
3.1 Positive	Industry funding supplements other sources of funding	(1) “It added another potential source of funding for our research. For well targeted projects, of interest to industry, the likelihood of obtaining funding was considered to be higher than through traditional funding bodies.” (2) “Excellent funding with well supported studies and the desire to prove the efficacy of therapies that I am using or to take the opportunity to bring new therapies into the clinical arena.”
3.2 Negative	Insufficient funding from other sources, negative experiences with other funding sources	(1) “Need for funding after multiple frustrating experiences with other funding agencies.” (2) “Large clinical trials are expensive and NHS/government/charity sources frequently cannot cover all costs.” (3) “An additional source of funding given the bleak current outlook.”

		(4) "Funding for a development project which would have been near impossible from charities or Research Councils."
3.3 Personal	Personal financial gain through consulting or other fees.	(1) "Consultancy fees helped pay for my children's education." (2) "To provide consultancy services for a fee through ISIS."
3.4 Neutral	Funding mentioned without context	(1) "Obtaining funding for research." (2) "Research funding for basic science and translation of basic science findings into novel medicines."
Theme 4: Scientific interest		
4.1 Interest	Research of personal scientific interest for the advancement of science	(1) "Interest in the mechanism of action of their drug (GSK, Roche)." (2) "It seemed like an exciting project, participation in which, would broaden my expertise."
4.2 Innovation	More freedom or innovation in research	(1) "Provided virtually complete freedom to innovate and follow the best leads." (2) "Traditional granting bodies don't "get it", because they are usually way behind the curve in terms of what we need to do, and only now are some of the changes initiated almost a decade ago getting into the mainline consciousness."
Theme 5: Education		
5.1 Studentship	Funding/joint supervision of students	(1) "Support of a DPhil studentship in an area of mutual interest." (2) "Co-development and supervision of projects." (3) "Educational benefits and student internships to add value to an MSc."
5.2 External training	Teaching and training of external stakeholders, e.g. patients, NHS	(1) "Our educational collaborations reflect a mutual interest to deliver high quality teaching to doctors and other health care professionals."
Theme 6: Access		
6.1 Facilities/reagents	Access to facilities or reagents not available easily in academia, especially drugs and compounds	(1) "To access resources to conduct translational studies - access to drugs to be used in clinical trials, access to innovative technology before it is available widely, financial resource, access to infrastructure provided." (2) "Access to information and equipment that requires a direct link with the manufacturers and developers." (3) "The population I wished to study required a particular type of drug to ensure safety. No such drug was available on the market at the time of study planning, but the industrial partner had one in development." (4) "They have a drug I wanted to use"
6.2 Knowledge/expertise	Access to knowledge, information or expertise developed by	(1) "Collaboration with industry groups with expertise in the design of high-throughput phenotyping screens for drug development"

	industry. Desire to work with a specific team/group	(2) "Pharma companies have way in excess of 95% of clinical trial data in [research field]. We have found industry often to be receptive, not only in providing data, but in providing funding for the work we do."
Theme 7: Leverage		
	To gain leverage for government funding, to satisfy requirements for Research Council funding	(1) "Access to novel early stage technologies and funding streams e.g. HICF and TSB." (2) "To Raise money for non-industry funded research."
Theme 8: Influence		
8.1 Industry product development	To influence industrial research	(1) "To have a continued relationship with industry to understand and have some influence on pharmaceutical product development." (2) "Ability to influence appropriate product development for patient care and use in a laboratory."
8.2 Uptake of methods	To encourage industry to uptake methodology developed by the academic	(1) "To increase the awareness and uptake of methods developed in my group by the pharmaceutical sector." (2) "To push method / technical developments."
8.3 Wider audience	Working with industry raises the profile/reach of the research	(1) "Potential to substantially raise the profile of the research, assisting in dissemination."

Where possible, examples chosen are responses that fit entirely within that category, however as each response was assigned up to four codes in some cases this is not possible.

Moreover, within 'Negative' comments one recurring theme was for industry to fund research that would otherwise be unable to occur, to essentially 'plug funding gaps'. This indicates that industry plays an important role in the translational 'eco-system' as research progresses towards the exploitation of new knowledge and technologies for patient benefit. From this perspective, industry can fund research that is outside the remit of charities and Research Councils, potentially enabling a greater diversity of research to be undertaken, research that is scientifically exciting to academics (Table 3.2, theme 4.1 'Interest'). Indeed, it was mentioned by academics that industry is willing to fund riskier, more innovative projects than Research Councils, which sought more certainty in the predicted outcome of their research (Table 3.2, theme 4.2 'Innovation'). This is a surprising result, and highlights industry research as valuable, contradicting common perceptions of industry funded research as 'adverts' for its products (Alexander, 2011).

The theme 'Translation' (Table 3.2, theme 1) was primarily mentioned as a motivation for collaboration in two key contexts. Firstly, responses mentioned the desire to follow through on their research and be personally involved in the development and exploitation of their findings. These responses were coded under theme 1.1, "Development and Application". Secondly, responses discussed the idea of translating research towards the ultimate endpoint of 'patient benefit' (Table 3.2, theme 1.2), though this was less commonly mentioned. In fact, the concept of patients or public benefit was only mentioned nine times in total across the entire survey, and in all instances the respondents had medical qualifications in addition to PhDs. This implies that the motivation of patients benefiting from translational research was not a key driver for many clinical academics, with only one in eight citing it as a motivation, and perhaps not a driver at all for non-clinical academics.

The third most common motivation to collaborate with industry was 'Access' - a means to gain access to otherwise difficult to obtain resources (Table 3.2, theme 6). Access, especially to reagents, was often seen as important to the progress of academic research, and was frequently mentioned as a way to gain a competitive advantage on other research groups. Where access to reagents was needed, it appears that the interactions are initiated by the academic with the

specific aim of obtaining a drug or data, perhaps resulting in more transactional (as opposed to collaborative) interactions. Conversely, access to industry knowledge, information or expertise was generally mentioned in conjunction with the benefits of synergy or mutual interest. Thus, the data potentially indicate that the sharing of complementary information is more conducive to genuine collaboration than the sharing of reagents, which is in agreement with findings from other studies in the literature (Nelson, 2009).

Respondents also described collaborating with industry to gain 'influence', discussed in three contexts. Firstly, in directly influencing industry practice, by encouraging the uptake of technology or methods developed by the PI. Secondly, in influencing industrial areas of research, by encouraging industry to focus their R&D efforts in similar areas. Thirdly, academics sought to raise the profile of their research via the publicity gained through collaboration with industry. Thus, in this data influence as a motivation was not mentioned in the context of influencing the opinions of colleagues, other academics within the University, but more in terms of external influence of industry, policy and the public. In the literature, the influence of external groups arose as a motivation for industry partners, but was less common for academics, where influencing peers and colleagues was more commonly cited (Section 1.2.3). This may indicate a difference between collaboration in translational medicine and other fields, perhaps due to negative perceptions of pharmaceutical companies in this field (Smith et al., 2014) making collaboration less effective at influencing colleagues in a desirable way.

The remaining motivations encompassed the use of collaboration to gain leverage for alternative funding sources, and the provision of education for students or other professional groups. These motivations were mentioned less frequently, and in any case appeared to manifest in a similar way to those covered in the literature for other fields (Section 1.2.3.1).

In contrast to these motivations, some respondents also indicated that they did not want to collaborate with industry, but rather felt pressured by the institution in a way that detracted from their primary research focus. There were four such responses such to the survey, which, while

rare, do raise questions as to how this ‘third’ mission is changing university culture, and support studies arguing that the increasing university focus on commercialisation is detracting from its a priori objectives to educate and generate knowledge (Siegel et al., 2003, Valentin and Jensen, 2007). Thus, the circumstances in which industrial collaboration is appropriate and works best should be examined, as should the limits of its benefits (Banal-Estañol et al., 2015).

3.2.4 Types of collaboration with industry

All 169 respondents provided data on the types of collaboration for which they have received industry funding. The typology used was designed by Chin-Dusting et. al. (2005) and was chosen as it is relatively recent and relevant to biomedical translational research. It comprises six types of collaboration, the characteristics of which are assessed in Table 3.3 in terms of: the degree of formalisation, level of knowledge exchange, level of resource deployment and duration of interaction. These characteristics are informed by the original description of the typology, and by the review from Table 1.5.

In responding to this question, participants were asked to provide information on both the *different types* of collaboration for which they had received funding, and also the *proportion of their total industry funding* that each type comprises. For example, while an academic may receive industry funding for investigator-led research and for consultations, they may receive 90% of their funding for the former and 10% for the latter. The total amount of industry funding received was not asked for due to ethical restrictions, as this could potentially un-blind the study, compromising the anonymity of the responses.

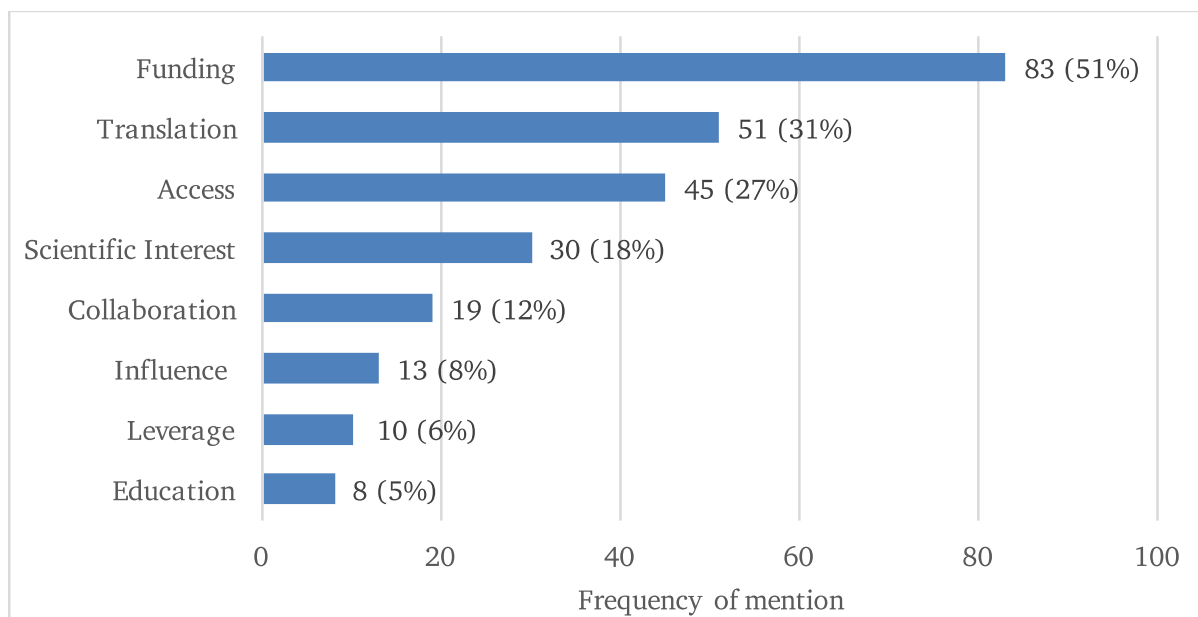


Figure 3.2 Frequency of motivations mentioned by respondents. In each case the actual frequency of the specific code is provided at the end of the bar, followed by the percentage of total PIs who were assigned that code. An overview of the codes are: ‘Funding’ - financial support was cited as a motivation; ‘Translation’ - desire for research to progress, or to provide patient benefit; ‘Access’ – PIs sought reagents, facilities, knowledge, or experts; ‘Scientific Interest’ - intellectual curiosity or an interesting project as a motivation; ‘Collaboration’ - concept of mutual benefit or complementary skill-sets as a motivation; ‘Influence’ - influencing industrial research focuses, encouraging the uptake of academic research methods and reagents into industry, and raising the profile of their research through industrial partnership; ‘Leverage’ - industrial collaboration was used to meet criteria or strengthen grant applications from alternative funders, such as Research Councils and charities; ‘Education’ - the education of either students or the external training of other professional groups was a motivation. Full description of all codes, sub-codes and definitions are provided in Table 3.2.

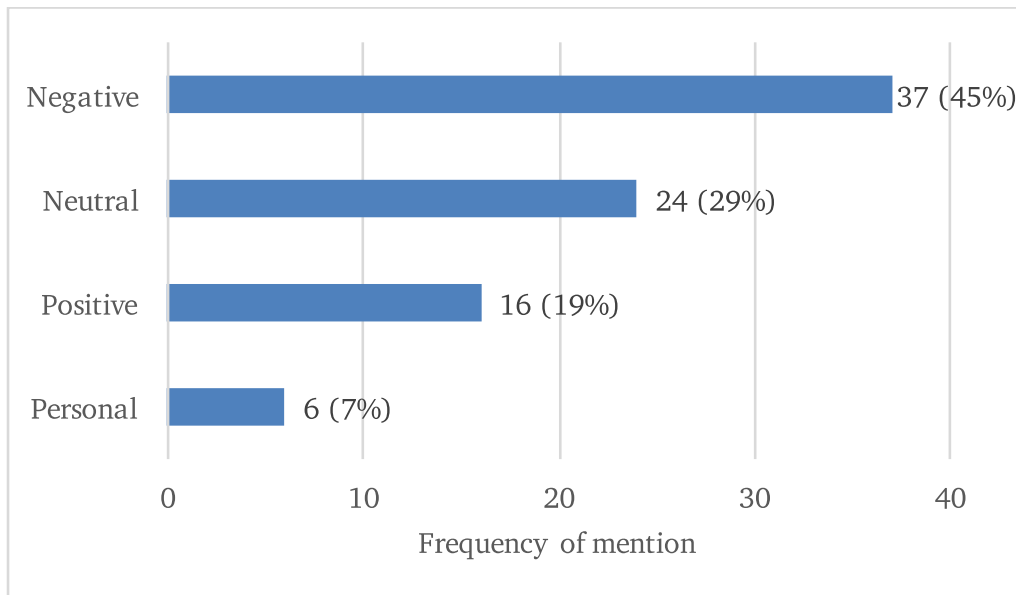


Figure 3.3 Analysis of responses mentioning ‘funding’ as a motivation according to phrasing.

‘Positive’ responses specifically refer to the abundance of availability of funding within industry; ‘Neutral’ responses mention funding as a motivation without context; ‘Negative’ responses highlight a lack of alternative, or conventional funding; ‘Personal’ indicates a response that specifically states collaboration for personal gain, e.g. through consultancy fees. A full breakdown of all codes and definitions, including examples is provided in Table 3.2.

By far the most common type of research was ‘industrial sponsorship of investigator-led research’, with 85% of respondents receiving some funding for this type of collaboration (Figure 3.4). Of those 85% of academics receiving this type of funding, it comprised the majority of their funding income, with the median proportion comprising 60% of total industry funding. ‘Industrial sponsorship of investigator-led research’ is the type of collaboration that provides for the most academic freedom, as highlighted in Table 3.3. This implies that most academics at the University of Oxford experience relatively high levels of autonomy in their industrial collaborations, and supports the literature that highlights the trend for academia-industry interactions to be increasingly based on genuine collaboration, rather than on a particular transaction (Section 1.2.2.1).

However, when considering consulting activities, which do tend to be more transactional, it is interesting to note the high frequency with which these occurred (118 PIs or 70% of respondents, Figure 3.4). This indicates that both academics and industry do still gain value from the exchange of knowledge for money. However, the value may well exceed that one interaction, as the vast majority of consultation activities occurred alongside other types of collaboration. Indeed, only one PI, or 0.6% of respondents, received their funding for consultations or fee-for-service research alone. Thus, it is possible that the exposure and opportunity for relationship-building afforded by consultation or fee-for-service activities could provide a basis for future interactions. In sum, the characteristics of consulting activities as high frequency and representing a low proportion of total funding implies it may be a ‘gateway’ activity, an initial interaction upon which more involved collaborations are fostered. In this way, transactional industry interactions could potentially develop into genuine collaborations.

However, the extent to which this hypothesis can be pursued is limited for two reasons. Firstly, the survey data do not indicate the temporality of the different types of funding received, and consulting may well occur as a result of collaboration, rather than vice versa. Secondly, no comparable data is provided on the extent of consulting activities amongst PIs generally in MSD and MPLS. A survey of PIs working in translational medicine generally, or all PIs who have

conducted consultancy and fee-for-service activities, would provide further insight should this hypothesis be pursued.

All other types of collaboration, including collaborations between academia, industry and the government, industrial sponsorship of training and education programmes, competitive industry sponsored grants and institute-institute liaisons were all mentioned by approximately 50% of respondents, and comprised between 15-25% of total industry funding.

Finally, data shown in Figure 3.5 demonstrate that the majority of respondents (78%) received industry funding for two or more different types of collaborative activity. This supports the notion that initial collaborative activities provide a basis for subsequent industrial interactions of a different (and perhaps closer) nature. Alternatively, it may be the case that several companies work in similar areas, identify PIs in similar ways, and thus contact the same high-profile academics for collaboration. It is not possible to determine which of these is most likely from the data, and it may well be the case that both of these are true to certain extents. Furthermore, while the total number of collaborations for each PI is not known, the seven academics who had received funding for all six types of collaboration may be representative of 'super collaborators', academics who have experience of a wide variety of different types of collaboration (D'Este and Patel, 2007), and could be a potential source of information for researchers seeking to understand the characteristics of such academics (Section 1.2.3.1).

Table 3.3 Types of collaboration used in survey and features

Type of collaboration	Degree of formalisation	Level of knowledge exchange	Level of resource deployment	Relational involvement*	Duration
Industrial sponsorship of investigator-led research	Medium	Medium-High	Medium	High	Medium-term – Long term
Consultations and fee for service including contract research outsourcing	Medium	Low	Low	Low	Short-term
Academia, industry and governmental partnerships	High	High	High	High	Long-term
Industrial sponsorship of training and education programs	Medium	Low	Low	Medium	Short-term
Competitive grants sponsored by industry	High	Low	Medium	High	Medium-term
Institute-institute liaisons developed on the basis of joint key strategic areas	High	High	High	High	Long-term

*Relational involvement (Perkmann and Walsh, 2007) relates to the extent to which interactions tend to be based around relationships, where

- High RI is where links are based on relationships: individual and teams from both institutions work together on specific projects to produce common outputs (e.g. Research Partnerships)
- Medium RI is when links are based on mobility (Academic entrepreneurship and human resource transfer)
- Low RI is when links are based on transfer (Commercialisation of IP)

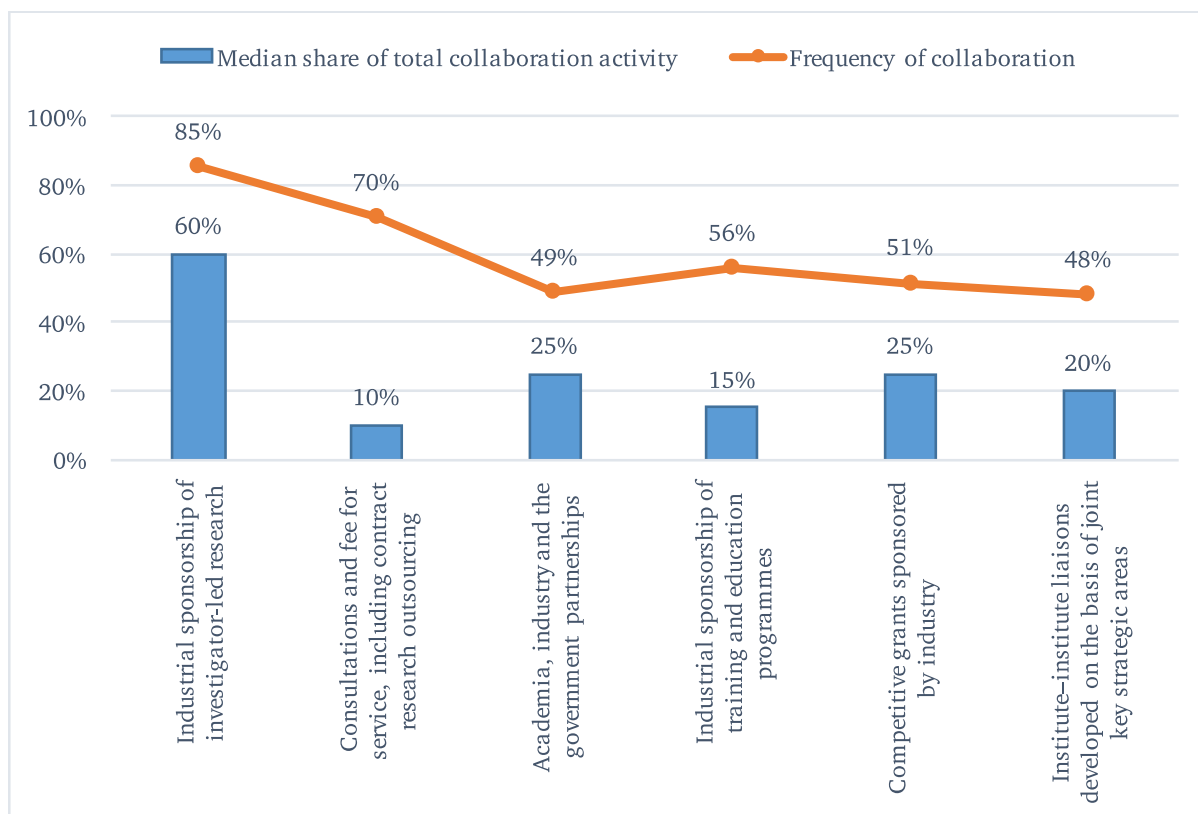


Figure 3.4 Types of academia-industry collaboration for which academics have received funding.

The orange line demonstrates the frequency of the collaboration (i.e. the proportion of PIs that received that type of funding). Of those that have received a certain funding type, the blue bars shows the average proportion of total industry funding obtained for that type of collaboration.

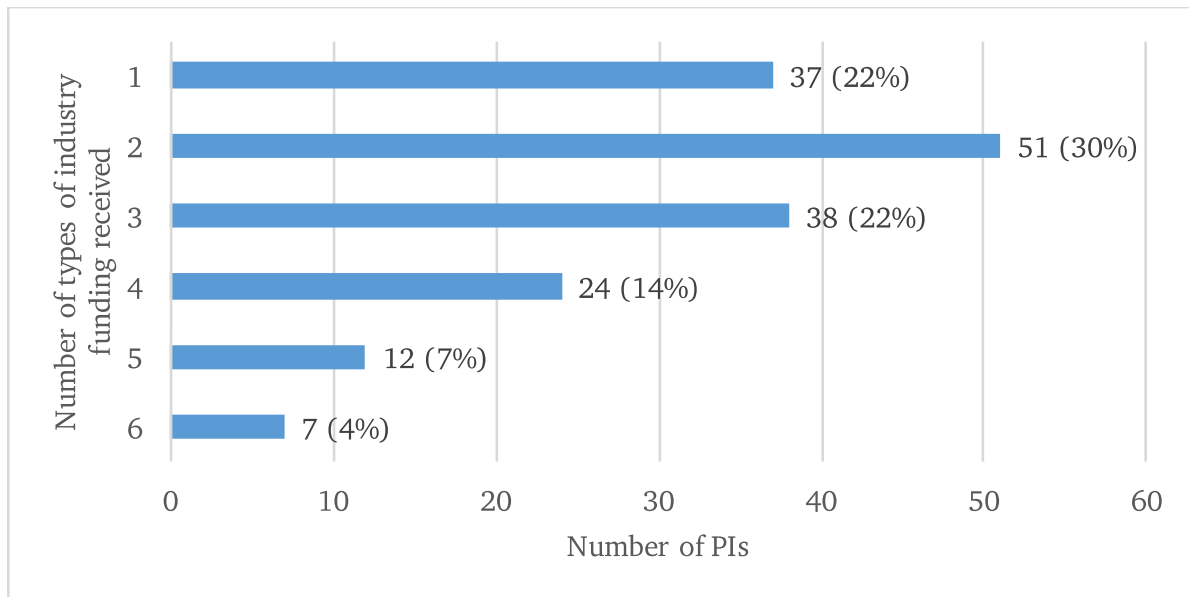


Figure 3.5 The number of different types of industry funding received by individual PIs. Data includes any proportion of total funding that is 1% or greater. Number on the end is the absolute number of PIs, the number in brackets is the percentage of all 169 participants.

3.2.5 Phases of translational research

The phases of translational research is based on the typology developed by Waldman and Terzic (2010), which encompasses development from early pre-clinical testing to large scale global health interventions. It is divided into six stages: T0 (the earliest stage, comprising basic, non-clinical or pre-clinical science) through T1-4, to T5 (the latest stage, encompassing social health care, political security and economic opportunity). A full description of each of the stages can be found in Figure 3.6. This typology was selected instead of the conventional clinical trial phases as it encompasses the entire development process, and ensures that both clinical and non-clinical academics are working from the same understanding. In order to provide guidance when determining the phase of their research, PIs were provided with Figure 3.6 in the questionnaire. Respondents volunteered information on both the *different development phases* for which they receive funding, and also the *proportion of their total industry funding* that each phase comprises. For example, an academic may have received funding for both T0 and T1 research, of which 80% of their funding was for T0 research, and 20% was for T1 research. During the presentation of results for this section, the terms 'phase' and 'stage' are used interchangeably to refer to the step in the translational process to which the research has been developed.

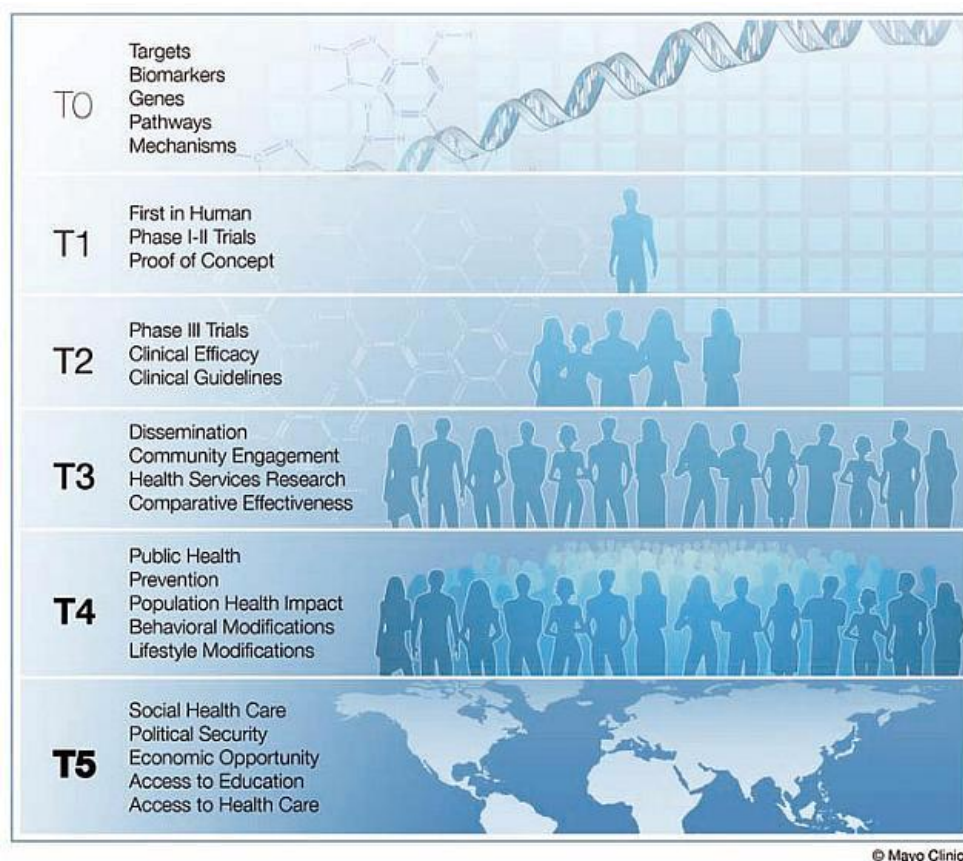


Figure 3.6 Phases of translational development. Phases were originally described by Waldman and Terzic (Waldman and Terzic, 2010) and were presented to PIs when responding to the survey.

All 169 respondents provided data on the development phase of their industry funded research. Over 79% of PIs received industry funding for early phase or T0 research (Figure 3.8), which comprised a median of 80% of their total industry funding. This indicates that industry is more commonly engaged with research that is less mature, and therefore still requires a substantial amount of investment and development before it can be commercialised. Furthermore, the probability of successful commercialisation is low due to the high attrition rates throughout clinical development, thus, the commercialisation of academic research seems an unlikely industry goal of collaboration. It may be the case then, that academia-industry collaborations in translational medicine seek to improve understanding of more basic research questions than to develop a specific therapeutic. This feature is surprising given the results from the literature review highlighting the majority of industrial collaborations in both the US and UK as being based around clinical medicine (Section 1.2.2.1).

Additionally, in contrast to the previous section where PIs received funding for multiple different types of collaboration (Section 3.2.3), in this case 40% of respondents received industry funding for research in a single phase. Of those, 80% received all of their industry funding for T0 research, by far the most commonly funded phase of research (Figure 3.7). Due to the high proportion of respondents in T0, further division of this section into smaller sub-categories may have provided additional insight into stage of research development. In the chosen typology, the category of T0 is very broad, encompassing research from target identification to phase I clinical trials. This limits the extent to which the characteristics of industry funded research in translational medicine can be accurately described.

When considering the dataset holistically as presented in Figure 3.7, there appears to be a trend indicating that the more mature the phase of research (i.e. the greater the “T” value), the fewer PIs receiving it, and the less likely it is to constitute all their industry funding (Figure 3.8). Only 7% of respondents received any funding at all for global health (T5), the most developed phase of research, and for those PIs that did receive funding for T5 research, it comprised a median of 10% of their total industry funding. None of the respondents received all of their industry funding for

research in the T5 stage of development (though this may be a result of the nature of research conducted in an academic institution, rather than a trait particular to translational medicine). Furthermore, as previously stated, data on the total value of industry funding received was not able to be collected due to restrictions in ethics approval. This data would have added meaningfully to this data, as each phase is treated equally in this analysis. However as shown in Figure 1.1, the complexities associated with each phase differ in terms of the required investment, with resource deployment and commitment generally increasing as translation progresses. For example, increased costs are associated with the transition from pre-clinical to clinical research, due to requirements for larger animal models and the use of GMP-grade instead of lab-grade reagents. These costs escalate throughout clinical stages due to increases in patient numbers and quality and regulatory requirements. Thus, even though there are fewer PIs receiving funding for late phase research, the total funding received may be significantly greater than for early phase research.

3.2.6 Advantages of Industry Funding

A total of 163 PIs (96%) responded to the open-ended question “In comparison with funding from government and charities, what have been the advantages and disadvantages of industry funding to your research?”. Both the advantages and disadvantages were analysed in the same manner as the motivations, i.e. inductive and deductive thematic analysis conducted independently by two researchers (Gale et al., 2013, Srivastava and Thomson, 2009). This process resulted in the elucidation of nine parent codes comprising a total of 15 themes (Table 3.4).

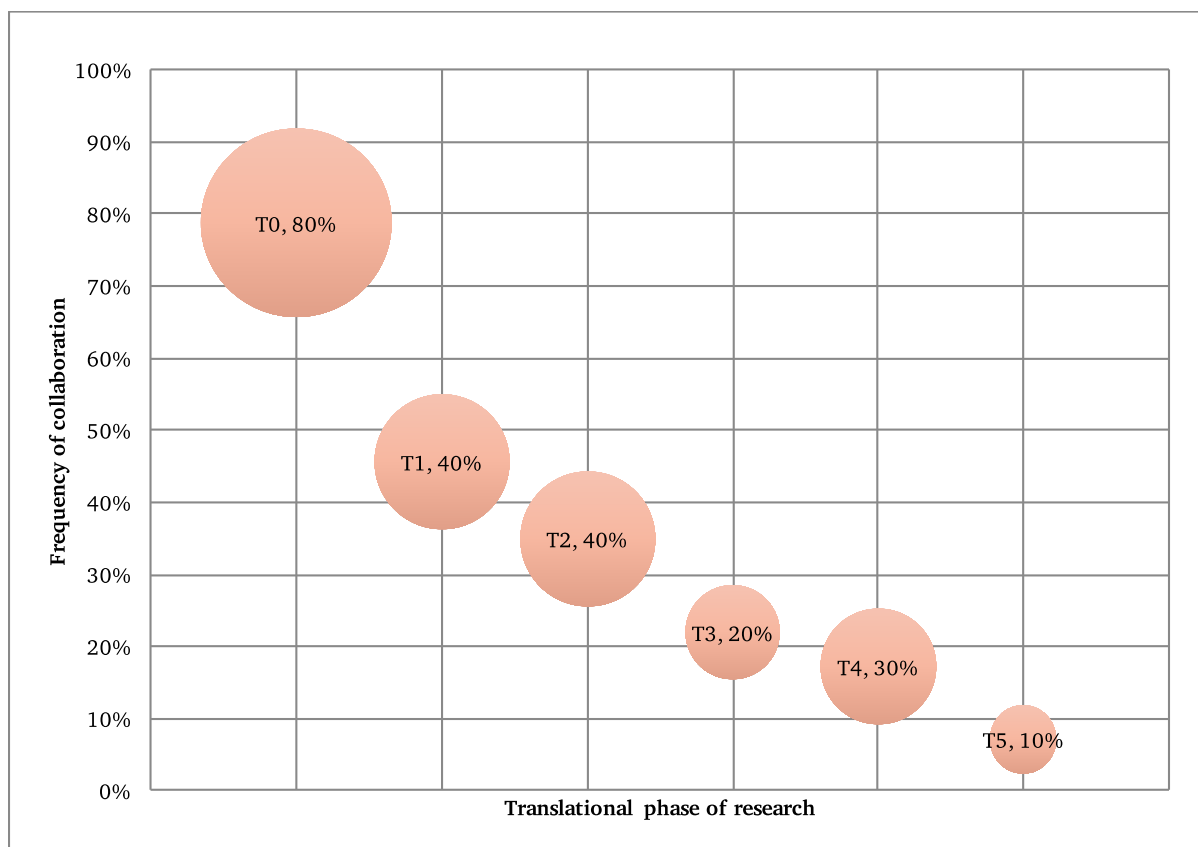


Figure 3.7 Overview of types of academia-industry collaboration. The size of each bubble is proportional to the median percentage of total industry funding received for that phase, also stated as the number inside the bubble. The intersection of the centre of the bubble and the Y-axis indicates the proportion of PIs receiving any funding for this phase of research.

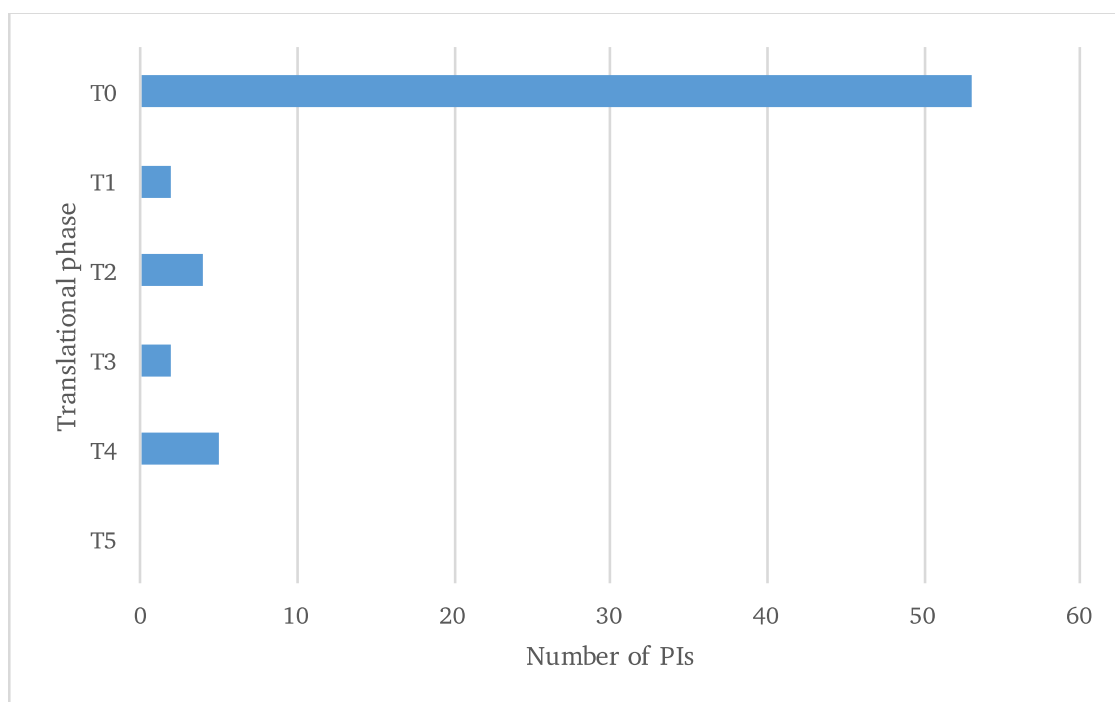


Figure 3.8 Number of PIs receiving 100% of their industry funding for research in a single development phase.

When analysed for frequency, as shown in Figure 3.9, the principal advantages mirrored the main motivations for entering into collaboration with industry. In particular, the themes of ‘Funding’, ‘Access’, ‘Collaboration’ and ‘Translation’ featured prominently in responses to both questions. The repeated measure afforded by this overlap provides cross-validation, indicating consistency among responses, and suggesting that these two analytical frameworks could be combined to encompass more generally the positive aspects of collaboration (see discussion) (Littell et al., 1998). As ‘Access’, ‘Translation’ and ‘Collaboration’ were coded to the same effect for motivations and advantages, (including, in the case of ‘Access’, with identical sub-codes), they are not further discussed in this section.

The frequency data shown in Figure 3.9 highlight ‘Funding’ as the most commonly cited advantage, as was the case with motivations (Section 3.2.3). However, from this code three different corresponding sub-codes emerged: the flexibility of industry funding, the abundance and availability of industry funding, and payment of overheads covering the Full Economic Costs (FEC) (see Section 1.2.4 for more insight into FEC). The first two of these sub-codes broadly corroborate with the findings from the motivations, in which ‘funding’ was often mentioned with relation to the relative abundance with which it is available from industry (Table 3.2 and Figure 3.3). However, paying the FEC of a project had not previously been highlighted as a positive aspect of collaboration. In general, universities require industry funding to attract higher levels of FEC (at least 100%, if not higher) compared with charity and Research Council funding. In responses to this question, overheads are mentioned as an advantage (Table 3.4, Section 8.1), although the data does not instruct as to how the academic benefits from the payment of high overheads, or why they are perceived as advantageous, as academics do not directly receive these funds. Rather, overheads are absorbed by the university, however a proportion may flow back indirectly to the academic through departmental funds. However, It may be the case that the payment of 100% FEC provides additional non-financial benefits, such as positive regard from departmental administrators. In a similar way, the theme ‘Focus’ was coded to 9% of responses, yet from the data available it is not possible to determine precisely how this benefits the academic (beyond

perhaps obvious inferences of clear aims). Responses coded under the theme 'Focus' mentioned the transparency and clarity of objectives for industry-funded research in comparison to other funding sources. One response stated that the result of such focus was "improved project workflow". This could be understood to relate to increased productivity from the research group, and a more transparent perception of progress. Additionally, this theme appears to contradict with threads in the literature which highlight the value of academic freedom to determine the course of their own research (Finkin, 1982, Aghion et al., 2008).

Another parent-code that encompassed aspects of funding was 'Easier', which emerged from responses highlighting the comparative ease with which industry funding is obtained and managed in comparison to Research Council or charity funding (Table 3.4, Section 3). 'Easier' was applied to 37% of responses (Figure 3.9), and comprised two sub-codes relating to 1) the initiation and 2) the maintenance of collaborations and funding. Numerous respondents highlighted the comparative simplicity of receiving industry funding, often in terms of reduced paperwork and the time savings, benefits that seemed of substantial value to respondents. The academic is not gaining any additional insight or collaborative advantage by working with industry, but instead benefits from faster access to funding, and the ability to concentrate on their research. Perhaps this perception is not so much a benefit of industry funding, but, in a similar way to needing industry funds for more innovative research, more reflective of disadvantages associated with the processes by which conventional funding is awarded.

The theme of 'Innovation' relates to industry funding research projects that would otherwise be unable to occur, in particular because they are too 'risky' or uncertain to be eligible for funding from Research Councils or charities. This adds weight to the idea previously postulated Section 3.2.2 that industry plays a vital role in the translational eco-system. There are research projects and hypotheses that PIs would like to investigate but believe are not covered in the remit of conventional funding bodies. Understanding more about the characteristics of this type of research could be an interesting development in determining, or at least delineating, where academia-industry collaboration may be most appropriate, and could facilitate academics more

generally in the pursuit of appropriate research funding. It may also provide an opportunity for Research Councils to reflect upon their remits based upon their missions.

The parent code 'Responsive' was assigned to 28 individual responses (Table 3.4, Section 5). Responses coded under this theme generally referred to the quick response time (under the sub-code 'Responsive'), or increased levels of active engagement (under the sub-code 'Engaged'), in comparison to Research Councils or charities. While on the surface similar to 'Easier', 'Responsive' differs through an emphasis of the personal or social benefits of industrial collaboration. Respondent described how having more engaged funders enables a relationship to form and trust to build. With industry, an academic can 'pick up the phone' to a specific contact and discuss the value of their research, whereas with Research Council funding multiple processes must be navigated, many of which are often anonymous. Furthermore, the opportunity for face-to-face interactions or the rapid back and forth between partners ensures the provision of quick responses, and these heightened levels of engagement may imply that PIs are more valued or prioritised in these interactions than in those with conventional funding bodies. One academic described a benefit as ["Closer relationship with industry than research boards/reviewers."], which, in a similar way to 'Easier', possibly implies that industry funding is easier to achieve or justify on the basis of a pre-existing close relationship - a level of 'trust' that exists between the academic and the industry partner. This quote is also indicative of another theme - 'Network' (Table 3.4, theme 6).

'Network' comprised responses that mentioned the benefits of making industrial connections and forming long-term relationships with industry. In some aspects this code is complementary to 'Influence', as identified in motivations (Section 3.2.3), in that it encapsulates the benefits gained beyond the single collaboration, and in particular the use of such relationships as social capital. One academic stated: ["Relationship fostered with certain companies. Ability to change their views... Line of sight to changing clinical practice"]. This implies that the Network/Influence codes are representations of the dynamic back-and-forth between PIs in academia and those in industry. Furthermore, this example has two additional implications. Firstly, there is a

temporality to the response – it seems this academic has a longer term plan built on the collaboration. Secondly, this response seemingly highlights the importance of industry in influencing clinical practice. Again, the themes of influence and network encompass responses that surpass the individual collaboration for more long term benefits.

For themes of ‘Easier’, ‘Responsive’ and ‘Network’ there is an overriding sense of improved communication and ease of access with people in industry, a point linked to finding one’s working life to be “meaningful” – as people are listening to, and even invested in, one’s research. However, the conduct of high levels of communication require traits that may not be valued in academia: charm, communication, persuasion, etc. Thus it may be the case that collaborations with industry might suit certain kinds of people in academia more than others.

3.2.7 Disadvantages of Industry Funding

A total of 161 PIs (95%) responded to the question “In comparison with funding from government and charities, what have been the advantages and disadvantages of industry funding to your research?”. From the analysis of qualitative responses, eight parent codes were identified, comprising 19 sub-codes in total (see Table 3.5 for full descriptions of codes and sub-codes). Where possible more examples are shown for disadvantages than were shown for advantages or motivations as this is the only open-ended question addressing negative aspects of collaboration. The frequency with which each of these codes was used was calculated and is shown in Figure 3.9.

Table 3.4 Overview of themes identified from responses to advantages

Code description		Example Quotations
Theme 1: Innovation		
Industry willing to fund studies that other sources won't fund, especially riskier studies		(1) "This has allowed us to continue research independently of the research funding bodies and to develop a novel line of investigation. The medical scientific community are highly conservative and resistant to new ideas whereas industrial funders in my experience are more open to pump-prime new ventures." (2) "Fund high risk areas of direct translational relevance but with possibility of low impact outcome." (3) "Funding for activities that would not be supported by government"
Theme 2: Focus		
Clear target/focus/goal		(1) "Clarity of agreement on objectives. Lack of external influence from scientific fashions or perceived public interest" (2) "Simpler and more defined research proposals and aims." (3) "Clear aims and good communication between partners at the outset and throughout the project leads to improved project workflow. More personal project development (face to face meetings) and more transparent project appraisal"
Theme 3: Easier		
3.1 Simpler to Initiate	Simpler to initiate (i.e. easier negotiations, less peer review)	(1) "Often a quicker decision. Easier application process usually with timelines that are less restrictive." (2) "Frequently funding is awarded quickly without complicated and time-consuming grant applications." (3) "No need to write unbelievably complex proposals."
3.2 Less on-going bureaucracy	Less on-going bureaucracy and reporting than non-industry funding	(1) "Often less bureaucracy and fewer grant reports to write" (2) "In our case the industrial partner exercises a quite light touch control. Research funding is provided in form of a blue skies grant. Updates are in form of phone calls & annual face to face meetings...We have their support/expertise/financial backing when interacting with regulatory bodies or when ready to proceed to phase I and POC studies."
Theme 4: Translation		
Increased likelihood that research will result in impact/patient benefit.		(1) "The projects are usually more close to the late stage of translational study and clinical application...The projects are usually carefully selected with higher potential leading to application products" (2) "Projects can be developed from proof of principle through to clinic and ultimately to product licence"
Theme 5: Responsive		
5.1 Engaged	Input and support from industry improves project	(1) "Freedom to innovate; enthusiasm of the sponsors for the research done and future implications." (2) "Intense, face-to-face due diligence as a review process of proposed programme..." (3) "Iterative process with meaningful engagement"

5.2 Responsive	Quick to respond and provide feedback	(1) "Quick response time. Face-to-face interactions. Frank feedback and avoidance of poorly informed and superficial peer reviews." (2) "Speed of decision making"
Theme 6: Network		
Collaboration builds relationship with industry.		(1) "A direct relationship with people who can help progress research" (2) "Better relationship with equipment suppliers." (3) "Relationship fostered with certain companies. Ability to change their views... Line of sight to changing clinical practice." (4) "Closer relationship with industry than research boards/reviewers."
Theme 7: Access		
7.1 Facilities/ Reagents	Access to facilities or reagents not available easily in academia	(1) "Access to novel drugs that would not be available without Pharma links" (2) "Access to latest equipment and resources compared with academic infrastructure."
7.2 Knowledge/ Expertise	Access to industry knowledge or expertise	(1) "Easier access to information on the company's product and being updated about any potential changes to the product in advance." (2) "Access to teams of people/technicians, often with one person only in academic lab."
Theme 8: Funding		
8.1 Overheads	Industry pay overheads in entirety (FEC)	(1) "Recovery of the full economic costs of a project" (2) "The departmental overheads are higher than with charities."
8.2 More funding	More opportunities, larger amounts of funding	(1) "Able to fund global trials often costing in excess of £100M" (2) "Substantial finance is available if the work is successful"
8.3 Flexibility	Funding more flexible, ability to spend funds as desired	(1) "Flexibility on use of funds within agreed research plan. Ability to negotiate additional funds if further work is warranted" (2) "Money more easy to spend and not restricted to categories. More freedom to spend what grant money is used for - e.g. buying a piece of equipment at short notice." (3) "Flexibility of funding, ease of securing funding on short timescale"
Theme 9: Collaboration		
Compatible research interests		(1) "Both parties working to achieve an agreed objective or set of objectives." (2) "Synergies working across university/industry boundary"

The most commonly cited disadvantage of industry funding in comparison with other funding types was 'Loss of control', mentioned by 36% of respondents. Responses coded under this theme described the restrictions that receiving industry funding place on academic freedom, through prescriptive research plans in specific areas and the inflexible pursuit of specific milestones. This code is significant as it disrupts the institutional value of academic freedom – that PIs have the ability to decide the focus and direction of their own research (Finkin, 1982, Aghion et al., 2008). A key distinction between scientists in academia and scientists in industry is the trade-off for money versus control (Industry, 2001). As shown by Stern (2004), academic researchers are willing to lower their salary in order to increase their research freedom. Thus in academia, the general perception may be that scientists are able to freely choose their research topic, in exchange for less remuneration and greater uncertainty of access to funds. Conversely, in industry, similarly qualified scientists tend to have higher salaries and greater access to research funds and resources, but are less free to choose the topic of their research, and indeed may need to shift focus according to company priorities. Responses coded under 'Loss of control' highlight instances where the balance of this system is disrupted. Where this disadvantage is highlighted, academics are compromising on their freedom in order to ensure the continuation of their research - there is a trade of academic freedom for funding, but without the certainty of continued funds or the personal benefits of increased salary. In this case, an academic may choose not to compromise on their academic freedom in order to satisfy the remits of Research Councils, yet may compromise on it regardless in the receipt of industry funding with its associated restrictions as they 'lose control'. Furthermore, if, as postulated previously, industry does play a crucial role in funding innovative projects (Section 3.2.3), then the academic may have no choice but to turn to industry if they wish to conduct this research.

However, it is possible that in considering the disadvantages of industry funding academics are overestimating the levels freedom enjoyed when conducting projects funded by Research Council. In this circumstance, instead of the research focus being influenced by the government's agenda (which affects academics whose research is beyond the remit of funding bodies), it is

influenced by the goals decided by industry. Therefore, it may be a case of ‘the grass is greener’, with each side assuming the other type of funding enables ‘more freedom’.

One respect in which there is a loss of freedom resulting from industry funding, which may differ from other sources, occurs once funding has been awarded and the collaboration has begun. The sub-codes identified within ‘Loss of Control’ (Table 3.5, Theme 3) indicate a discrepancy between the conditions imposed by industrial funders and the factors that contribute towards progress in academia. For example, the sub-codes of ‘Overbearing’, ‘Less innovative’, ‘Dependence’ and ‘Need to adhere to industry goals’ encompass themes of confidentiality, exclusivity and intransigence in receiving industry funding that could be in tension with the academic goals of innovation, publication and academic collaboration (Nathan, 2007, Oxford, 2012, Etzkowitz, 2003). The restrictions encompassed within this code, however, also contradict the motivations identified previously (Table 3.2, Theme 3), which highlighted industry as funding riskier, more innovative, research. Thus it may be the case that there are distinct groups within the survey respondents that have contradicting experience of industry funded research as being more or less innovative.

While the ‘Loss of control’ regarding the implementation of a specific research project was highlighted, at a higher-level respondents also mentioned the sensitivity of industry to external factors such as geopolitical changes. Indeed, even if there is coherence in aim and approach between the academic and industry partner, there may be the potential for further loss of control due to unpredictable changes in the market.

Linked to this point, the second most common disadvantage, mentioned by 25% of respondents, was ‘Risks of short-term outlook’ – highlighting the speed of change in industry. This disadvantage was mentioned in the context of either frequent changes in industry personnel, or changes in industrial circumstance/agenda that can result in the sudden withdrawal of funds. This code highlights the perception of industrial funding as being less secure than Research Council or charity funding. Indeed, even contracts put in place to protect academics may not effectively be doing so. Furthermore, short-term outlook was mentioned regarding the

expectation of a quick return on research investment, in contrast to research projects that might have potential to generate long-term benefits. Again, this potentially conflicts with the data discussed in Section 3.2.5, highlighting that industry-funded research tends to be very early stage. As with 'Loss of control', this tension could be due to the presence of distinct groups within the respondent population.

Another major theme that emerged was the practical difficulty in dealing with collaboration. Due to the high frequency of this theme (as shown in Figure 3.9, it was mentioned more than 60 times) it was split into two parent codes relating to disadvantages with the initiation ('difficult to set-up'), or maintenance ('on-going bureaucracy') of industrial collaboration. 'Difficult to set-up' encompassed two types of practical difficulties: a) due to complexities associated with the contracting process, in particular being too lengthy and putting the collaboration in jeopardy ("Contracts", Table 3.5, Section 1.1), and b) associated with finding the right people - knowing who in industry has the ability to form a collaboration ("Navigation", Table 3.5, Section 1.2). These barriers were mentioned by 22% of respondents, and were often discussed in terms of the impact they had on the collaboration. The contracting process in particular was identified as 'frustrating', and resulting in the loss of grants. With contracting, there also seemed to be a lack of understanding and transparency. Academics did not seem aware of why the contracting process seemed to take so long, especially in the case where the PI and Industry have already agreed terms.

Additionally, beyond the practical disadvantages of collaboration, some responses may indicate a deeper mistrust. Coded under 'Navigation', this sometimes emerged with concepts of fruitless meetings and wasted time. In some cases it was mentioned that academics feel they 'impart information' to industry without reciprocation. It could be suggested that academics feel vulnerable in their interactions with industry as they could arguably lose their most valuable asset – their ideas. Thus, the difficulty of finding the correct industrial collaborator is further complicated by a reluctance to disclose key information.

'On-going bureaucracy' concerned disadvantages that emerge once the collaboration has commenced. These related to the administrative burden, as encompassed in the sub-code 'reporting', and the strictness with which industry imposed timelines, coded under 'timelines'. Both of these potentially link to the concept of lost academic freedom with PIs unable to pursue their own interests and research agendas as they are under pressure to work to strict timelines, required to regularly report progress in meetings, unable to deviate from the agreed plans or free to pursue arising research questions.

Some of the disadvantages of working with industry were not due to the collaboration itself, but rather the perception of the research outputs by external parties – in particular colleagues. Such responses were coded as 'Less well perceived' (Table 3.5, Section 5). The concept of 'dirty money' was mentioned by several academics, with results seen as biased and generally afforded less academic kudos. 'Less well perceived' tended to be mentioned more by clinical academics than non-clinical academics (16% vs 10% respectively), which although not statistically significant ($p = 0.122$, Chi² test) is worth noting in the context of an open-ended response, where factors are given voluntarily without prompt.

The basis for the difference in peer perception of industry funded research may be related to 'Cultural differences and transparency', a theme that was highlighted as a disadvantage by 23% of respondents. This broad theme encompassed many different aspects, from a lack of understanding of constraints within both groups, to differing approaches to publishing. This theme highlighted trends of mismatched goals and incentives between academia and industry, and often illustrated how collaboration may only be appropriate within certain contexts. An improved understanding of the pressures of each side may make it easier to identify cases where collaboration will add value to research, where goals can be aligned.

Finally, the code 'Funding' includes responses that concern one of two factors: either reduced quantities of funding from industry, or the University overheads (primarily in terms of less than 100% overheads being paid, but where overheads were perceived as being too high). Mentioned

by 8% of respondents (Figure 3.9), the presence of this theme conflicts with the most commonly mentioned advantage, which was the availability of industry funding. For eight out of 14 responses coded under this theme, advantages from the same respondent were coded as 'funding'. While the advantages for these responses often related to the flexibility of funding or ease with which it is obtained, in two cases it was mentioned in terms of abundance. For example, one PI stated in advantages: ["Money more easy to spend and not restricted to categories. More freedom to spend what grant money is used for - e.g. buying a piece of equipment at short notice."], and in disadvantages: ["Detailed explanations of how grant will be spent with no flexibility while implementing the grant. Lack of funding to travel to conferences at short notice or employ someone for short period."]. While these responses may appear to contradict, it could corroborate with data on the Types of industry Collaborations, implying that PIs receive funding for more than one type of funding, and these may have different corresponding advantages and disadvantages. Furthermore, the availability of funding and amounts of overheads paid may be affected by other factors (e.g. size of company, R&D budget), which were not elucidated in the questionnaire. However, as such data were not collected via the survey instrument, these conflicting data do reflect a limitation of questionnaires, where the attribute cannot be linked to the characteristics of a specific collaboration experience. Interestingly, in addition to those themes already discussed, 12 PIs (7%) indicated in their response that there were no disadvantages to industry funding.

Table 3.5 Overview of themes identified from responses to disadvantages

Code Description		Example Quotation
Theme 1: Difficult to set-up		
1.1 Contracts	Long process to initiate collaboration due to contracting process, negotiations and IP agreements	(1) "Contracts in the University take such a long time, research is no longer relevant by the time the contracts are agreed" (2) "Lengthy contract negotiations between University and Industry lawyers (when PI and Industry have already agreed terms)" (3) "Complicated and sometimes very time consuming and slow internal (University) bureaucracy" (4) "Very difficult and time consuming for University to reach agreement with Industry. Usually takes longer than a year. Due to difficulty and time 2 large grants have been lost"
1.2 Navigation	Hard to find the right partner and many fruitless meetings	(1) "One spends quite a bit of time discussing projects, imparting information to them, and often nothing actually materialises" (2) "Endless meetings with 'interested' people from industry results in very few real projects agreed" (3) "You have to hold many meetings with many potential partners until you get a good match."
Theme 2: On-going Bureaucracy		
2.1 Reporting	Heavy administrative burden in terms of reporting etc.	(1) "Frequent reporting" (2) "Delays in presentations and publications whilst waiting for company lawyers to check papers even when both myself and my direct industry colleagues know there is no confidential information" (3) "Lots and lots of meetings. Enormous amount of time spent on teleconferences, and face to face meetings, SC, board meetings, project team meetings, pre and post meetings for all of the above. To keep everyone fully informed."
2.2 Timelines	Need to stick to strict industry timelines and milestones with little flexibility	(1) "Often fairly stringent time conditions" (2) "Rigid adherence to agreements and deadlines on the part of the industry partner while requests for flexibility are made to the academic partner." (3) "Can be milestone and academically inflexible."
Theme 3: Loss of Control		
3.1 Overbearing	Overbearing industry partner dominates project	(1) "The project was extremely micromanaged by the industrial partner" (2) "Risk of commercial interference in research" (3) "Unnecessary/excessive oversight of research by industry" (4) "There is a necessity for careful regulation of interactions between our group and the company, stressing our independence. There is often pressure to comply with processes or rules that are relevant to the company but not our group/unit."
3.2 Need to adhere to industry goals	Academics need to alter their goals to adhere to industry goals and protocols.	(1) "Projects are driven by specific aims mostly dictated by the industry partner, less flexibility in conducting academic research" (2) "Some loss of academic freedom i.e. the idea has to fit with the strategic view of the company." (3) "Tension between our goals and theirs. Lack of flexibility to combine projects"

		(4) "Funding is (largely) restricted to areas that are of interest to the companies. As a consequence, it may distort the research agenda with support for trials (and other studies) related to new treatments at the expense of trials of old treatments that would be of public health significance." (5) "Being at the mercy of the company's latest strategic priority which is not always compatible with finishing a piece of work to a standard of completeness required for publication"
3.3 Less innovative	Restrictions on scope/novelty of research and ability to work with other companies	(1) "Little scope for research outside very defined limits" (2) "Some decrease in our flexibility to respond to changes in how the field is moving. Need for their approval a few times per year in research direction."
3.4 Risks of dependency	Risks of becoming dependent on one company	(1) "Restrictions on further use of reagents to explore mechanistic aspects in more detail." (2) "Dependency on one or a very few companies"
Theme 4: Funding		
4.1 Insufficient funding	Funding provided is not enough to conduct research	(1) "Difficulties to obtain enough funding for Post Docs and PhD student" (2) "Limited funds available"
4.2 Overheads	Less than 100% overheads, tension with university	(1) "Funding is lower and does not cover overheads properly, hence not as attractive to department." (2) "University wants "overheads" that often bear no relationship to the reality." (3) "Can sometimes be difficult to convince companies over the size of university overheads which can be "show stoppers.""
Theme 5: Less Well Perceived		
5.1 Reduced kudos in academia	Research funded by industry not perceived as highly as non-industry funded research	(1) "Not always viewed as competitive funding by peers. Seen as soft money." (2) "university doesn't see as prestigious" (3) "Is not regarded as highly academically, therefore not helping much for an academic career" (4) "Some academics do not value industry funding compared to a Research Council grant. Occasionally there is suspicion that the researcher has something personal to gain when he/she is working on an industry funded project."
5.2 Biased, lower quality or corrupt	Research results seen as biased and less rigorous by academic community	(1) "Industry funding viewed negatively by medical journals and at conferences as being biased research and not independent." (2) "Perceptions of some colleagues that such research is "polluted" or less valuable than non-industry funded research" (3) "Despite the obvious value of industrial partnerships the University of Oxford discourages any interaction with industry and describes such work as not being of any value and has a 'dirty money attitude' towards industry funded work. In a conversation with finance I was told that 'you do not do any research' despite producing more publications than anyone else in the Department." (4) "You may be seen as having a conflict of interests in reporting results"
Theme 6: Risks of Short-Term Outlook		

6.1 Risks of withdrawal	Potential for sudden withdrawal of funding/support due to company changing focus	(1) "[Industry] close their participation when the preliminary results were not satisfactory to them (they kept the funding)" (2) "Industry can change its focus rapidly and lose interest in the project" (3) "Changes in industrial focus - project terminated early" (4) "Companies may change their plans or go out of business so the collaboration can come to an abrupt end even if progressing extremely well." (5) "Projects can be cancelled at any time due to organisational restructuring" (6) "Change in strategic direction due to financial drivers. Key collaborators leaving at short notice"
6.2 Risks of personnel restructuring	Frequent changes of personnel lead to lack of continuity	(1) "Industry priorities and personnel change very quickly" (2) "Staff turnover in industry is high so we sometimes lose point of contact on longer term projects" (3) "Fast turnover of staff" (4) "Turnover of staff in industry as they change roles within the company leads to lack of consistency"
Theme 7: Cultural Differences and Transparency		
7.1 Decision making	Difficulty understanding who makes the decisions and the basis for these decisions	(1) "Sometimes difficult to understand who makes decisions on funding in industry and why" (2) "Difficulty in understanding who has sign off powers to allow collaborations to happen. Multiple layers of management in industry."
7.2 Secrecy	Industry secrecy around data and product sharing	(1) "Industry secrecy concerning the data they already hold" (2) "Obfuscation rife, honesty and truthfulness sometimes compromised...can create greed and subsequent poor practice/management" (3) "Commercial focus, little scientific interest. Unspoken desire to bury results that go against commercial aims or are not commercially relevant in the short term"
7.3 Lack of understanding	Lack of understanding on behalf of both universities and industry on the pressures of the other side	(1) "Culture at Oxford sometimes has difficulties in appreciating how industry works" (2) "Working style is different and can be quite demanding." (3) "Poor awareness of industry regarding contemporary need for academic deliverables"
7.4 Publishing	Cultural differences in approach to research and publishing	(1) "The focus is to develop intellectual property via patents, and this must precede publication" (2) "Legal issues can be a huge headache, because pharma legal departments don't understand that open publication is essential at this stage. Different from early-stage research they usually deal with... [industry] just don't get the need for publication, and so there is a failure to progress." (3) "Less keen to publish negative results."

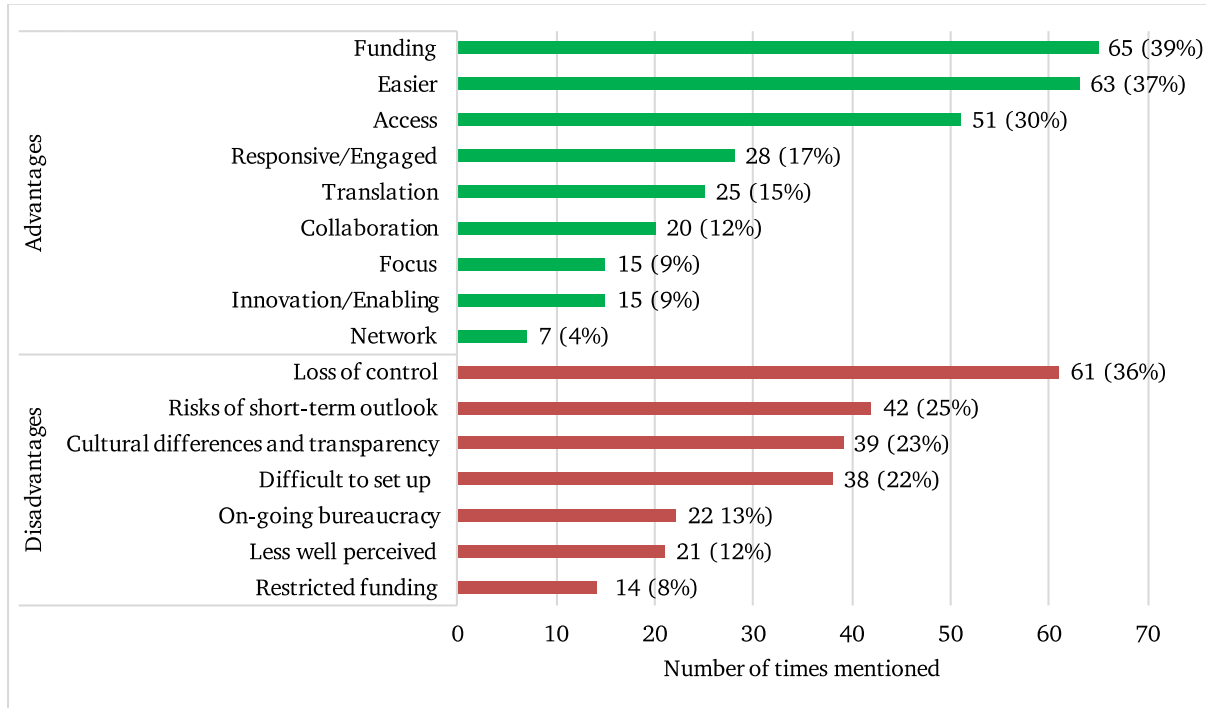


Figure 3.9 Frequency of advantages/disadvantages of industrial collaboration by all respondents.

The data labels at the end of each bar are the absolute number of times each code was mentioned, followed by the percentage of the 169 total respondents mentioning that response.

3.2.8 Barriers to Collaboration

Of the 17 barriers to collaboration pre-identified from the literature (Section 1.2.2.4), only three were recognised as barriers by $\geq 50\%$ of respondents to the questionnaire, highlighting the diversity of experiences among respondents. These three barriers were: 'Short-term orientation of industry research', 'Lengthy contracting process within the university', and 'Inadequate recognition and incentives within university' (Figure 3.10). It may be the case that the first two of these antagonise each other, i.e. the impact of short-term focus of industry research is exacerbated by the amount of time taken to establish the collaboration. These results correspond with the disadvantages from Section 3.2.7, in particular 'Risks of short-term outlook', 'Difficult to set up' and 'Less well perceived' (See discussion for further analysis).

The barriers that fewest respondents agreed with were 'Ethical issues related to receiving industry funding', 'basic science orientation of academic research' and 'perceived conflict of interest from university colleagues'. The first of these may be ranked low due to bias within the survey population, such that researchers who procure industry funding are less likely to perceive, or admit to perceiving, ethical issues with its receipt. Analysis of data from a similar questionnaire given to a control group of academics without industry interaction/funding may yield a different result. The low perception of 'basic science orientation' as a barrier agrees with the results presented in Section 3.2.5, which suggests that most industry funding is for research that is early phase (i.e. this is not a factor preventing collaboration). The low ranking of 'Perceived conflict of interest', when taken with the disadvantage 'Less well perceived' (Section 3.2.7), has several possible inferences. One inference is that while encountered as a disadvantage, poor perceptions due to conflicts of interest do not actively prevent collaborations from occurring or continuing, i.e. they are not a substantial barrier. Alternatively, 'Less well perceived' may be more related to the poor perception of the quality or validity of the research, rather than due to ethical concerns.

Barriers perceived as important by 40% or more of respondents related to publishing restrictions, the high costs and slow speed of academic research, conflicts over intellectual

property (IP) rights, and a lack of government funding. These barriers are diverse, but are faults generally attributed to the university or government rather than the industry partner. Thus, perhaps academics are sympathetic with the industrial position.

3.2.9 Strategies to Improve Collaboration

A total of 140 respondents (83%) provided suggestions for strategies to improve collaboration. From these responses, eight strategies to improve collaboration emerged (see Table 3.6). These eight strategies covered several different time points course of a collaboration, from finding initial industry partners (database, group, joint events), through to setting up and maintaining collaborations (contracts, mentor, overheads), to overcoming cultural differences and encouraging continuity of collaborations (personnel exchange, incentives and recognition).

Many of the strategies concerned helping PIs to identify appropriate industrial partners, with several academics using this open-ended question to reinforce this ‘navigation’ of industry as a key barrier. Additionally, some PIs felt that the levels of collaboration in the university were adequate, and were concerned about the university’s independence from industry goals. Other academics were concerned that working too much with industry may ‘devalue’ the Oxford brand, implying that there are negative connotations associated with working with industry. This may be linked to the ‘loss of control’ and the ‘negative perceptions’ incurred (Section 3.2.7), with several academics discussing how collaborations should occur only where they can have the most benefit, with minimal impact on academic freedom and independence.

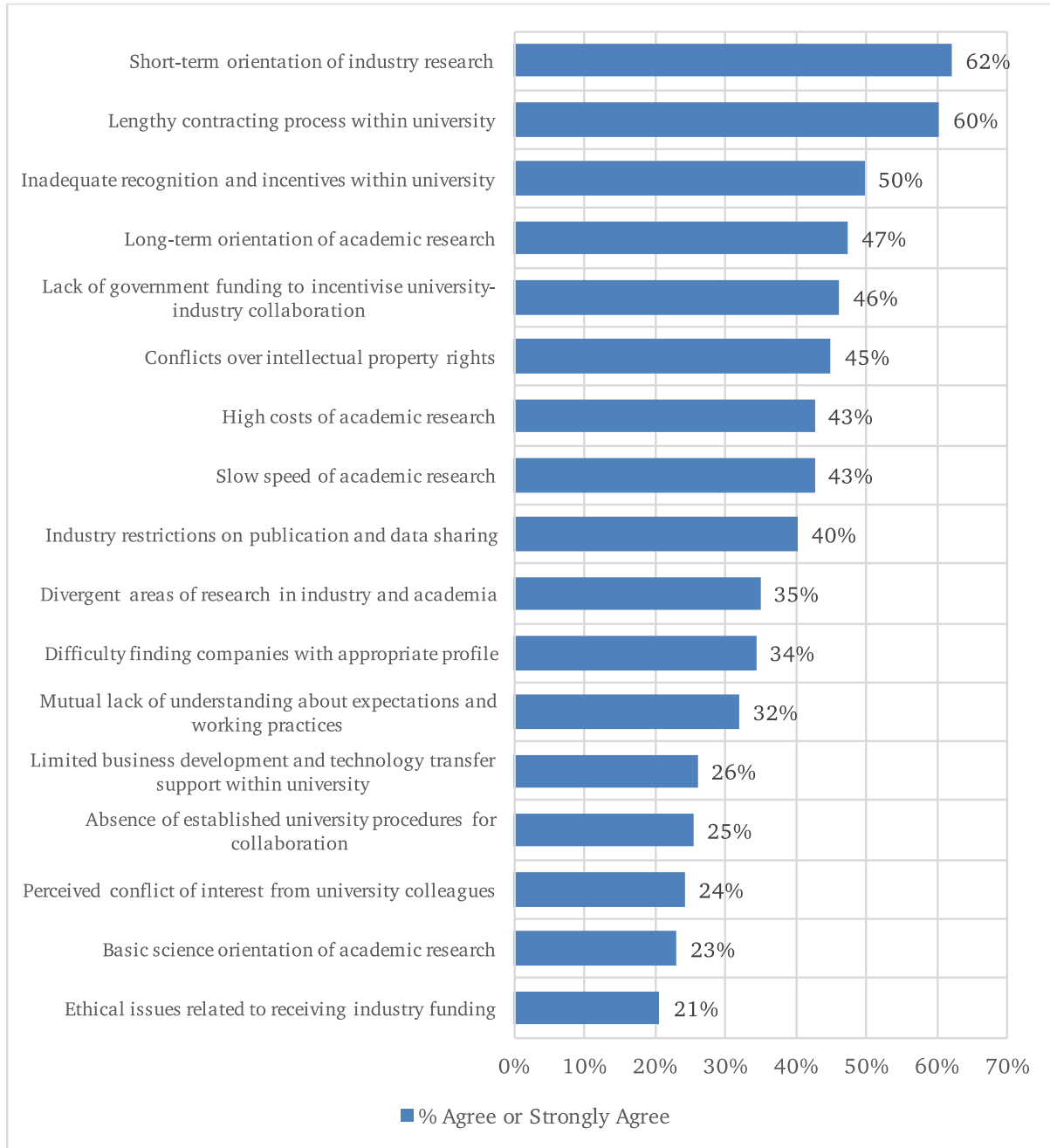


Figure 3.10 Percentage of respondents responding either ‘agree’ or ‘strongly agree’ to pre-identified barriers to collaboration. Barriers were identified from the literature review outlined in Chapter 1, and ranked on a five point Likert scale from ‘strongly disagree’ to ‘strongly agree’

The majority of strategies suggested were non-specific, hinting towards helpful outcomes (e.g. [“we need to create more opportunities to meet industry”]) instead of specific ways in which those outcomes might be achieved. This is most likely due to the phrasing of the question, was not captured during the piloting process and should be reviewed if this survey should be repeated in other departments or at other institutions. Not all strategies will be equally helpful, it may well be the case that academics, while a valuable source of information, are not best placed to suggest strategies to facilitate the collaboration process. Thus, it is important to consider which barrier(s) each strategy could address, to evaluate their potential effectiveness at doing so, in addition to assessing the feasibility and effort required to implement them (see Section 3.3.4). Furthermore, while these suggestions may form the basis of potential strategies, it is important to pitch these suggestions to one potential end user – academics themselves. This is conducted as part of the interview process in the next stage (Section 4.3.3).

Table 3.6 Overview of strategies identified from survey

Name	Strategy description	Example quote
Database	Create a database of all known industrial partners and their interests. AND/OR create a database of all academics in Oxford and what they're working on.	(1) "Industry is usually after a specific area of expertise. What would help is to provide information about specific area of expertise within the University that can be made accessible to industries that are looking for these. This will help to identify novel partnerships." (2) "Provide an improved 'one stop' website to better expose the diversity of basic bioscience research undertaken in Oxford to potential industry partners - they often simply do not know what is being done where within the University" (3) "Establish an easily accessible database of industrial partners with their research interests." (4) "The University might set up links with all UK Bioscience/Pharma companies, so that a 'directory' is immediately available for researchers, perhaps via ISIS Innovation to protect any new discoveries."
Group	Form a group or department within the university with the specific purpose of identifying, facilitating and maintaining partnerships.	(1) "If Oxford had an industry collaboration coordinating arm, which was regarded by industry and researchers as a very legitimate organisation that promoted high-quality and high-profile partnership projects then inexperienced investigators would be able to find support and encouragement and would also be less likely to feel that their integrity and independence might be questioned as a result of industry collaborations." (2) "Contracts definitely can be rate limiting, application process for govt grants often lengthy and requires financial and other programmatic support - can be challenging upfront. Perhaps a small team of administrators who are expert at writing such grants to support this stage (once granted can usually fund project manager from grant). Tech transfer input; If academics don't work regularly with Isis, contacting them 'out of blue' and engaging at short notice can be a challenge on both sides. Also high turnover of Isis staff, although they have been willing to help when asked."
Contracts	Streamline standard contracts to expedite the formation of partnerships (e.g. MTAs, NDAs, IP agreements)	(1) "There needs to be more streamlined processes for getting agreements into place" (2) "Collaboration can be encouraged, but it can be a lot of wasted effort when Industry changes tack mid negotiations. If the University could speed up the negotiations and contracts etc, it might be easier to ensure that the projects actually happen." (3) "The main focus would be on the contractual processes which are terribly slow and arduous and definitely impairs future collaborations" (4) "A rapid low cost contracts process would be beneficial in ensuring that more industry applications are granted particularly in interventional studies, where time is of the essence."
Joint events	Host targeted joint events to 'showcase' academic research and enable networking.	(1) "Create more opportunities to meet potential industrial partners by inviting them to Oxford events." (2) "University should promote visits by industrial research directors to the relevant university departments to see presentations of departmental research."

Personnel exchange	Increase exchange of personnel between academia and industry, by creating joint appointments, 'hot-desking', or encouraging sabbaticals.	(1) "Facilitate exchange of expertise by offering travel awards for academics wishing to spend time in industry" (2) "Provide space for companies to have a presence within the university, establish strong high level relationships with key industrial partners" (3) "People and "culture" exchange; the University/Industry could support industry sabbaticals for junior and senior research staff from both sides."
Incentives and Recognition	Establish an incentive system within the university that recognises or rewards academics for working with industry. E.g. recognition in grant applications, contribution to department, REF.	(1) "The university needs to convey more respect to the "importance and quality" of industry support. Almost all novel agents come from pharma not academia" (2) "Very simply making this as acceptable within the University as the grant based system for research." (3) "Vigorous culture change within the University's MSD but also within the NHS" (4) "Encouragement of PIs, and more recognition of this source of income" (5) "Change in culture; industry work and involvement is seen by many as problematic, even if conflicts are properly managed. Value creation needs to become more recognised as a goal in itself."
Mentoring/ Support	Use experienced academics to mentor junior researchers, especially where they have experience of collaborating with the same company.	(1) "Academic partners need training in how to engage with industry and how to access the support offered by the University research services for negotiating agreements." (2) "Support to understand what makes a 'good deal' or 'bad deal' with industrial collaboration. Training for researchers in how to manage/pitch ideas to industry (understanding the differences in goals and how these can be managed)" (3) "We need passionate, forward-thinking, clear-sighted LEADERSHIP that will inspire and enthuse our academic colleagues to engage with industry. Had it not been for [mentor's] guidance, we would not have succeeded. There were many obstacles; his relentlessly positive attitude and knowledge from his experience gave us the staying-power to overcome them."
Overheads	Reduce the cost of overheads within the university (either with a government subsidy or by reducing 100% FEC demands)	(1) "There needs to be more flexibility on overheads" (2) "Reduce the excessive overhead" (3) "Reduce FEC. It is ridiculous to ask for 100% if other universities ask for much less. We lose business that way." (4) "The University needs to be less interested in fully costing initial projects. This can result in industry canning good projects which could have led to bigger grants. If the University sector is to effectively support industry in the UK the government needs to make more funds available so these initial pilot projects get off the ground and the University can fully cover costs."

3.3 Discussion

The aim of this questionnaire was to answer the four research questions outlined in the introduction (Section 3.1). The data collected and the above analyses enable the following responses to these research questions:

Study question 1a) What are the characteristics of the PIs, and their research, in the University of Oxford who receive industry funding?

PIs receiving industry funding tend to be male, over 40 and have professorial titles (Table 3.1). Overall, research funded by industry tends to be in earlier phases of development (before clinical trials), and research projects tend to be led by the PI as opposed to the company. This is true both for clinical and non-clinical academics. The notion that more senior academics collaborate is consistent with the literature, however the observation of the ‘u-shaped’ curve was not identified, as the survey population did not include many junior academics who are early on in their career (D’Este and Patel, 2007). This may be due to differences in culture between translational medicine and other fields, where early career academics are more likely to work in areas within the remit of Research Councils, or have more concerns about damaging their reputation by involving themselves with industry. Alternatively, this may be due to a limitation of the data; more junior academics may be more likely to engage in informal interactions with industry without the exchange of funding. Unfortunately, without a comparator group of non-collaborating PIs it is difficult to determine how these features differ from other Oxford PIs, or to establish insight into why these PIs might be selecting to collaborate with industry. It would be interesting to conduct further research into this topic, in particular on the number of and impact factor of academic publications, as research in the literature demonstrates that this is often how industry identify PIs to collaborate with.

However, one factor that may impact the decision of academics to collaborate with industry is that the nature of the research they are conducting is translational, and therefore in order to best conduct it they require access to tools and expertise housed within industry. This is compounded by the perception that translational research is less likely to be funded by Research Councils, which may increase the pursuit of other funding sources. Thus, one area where academia-industry collaboration in translational medicine may differ from other fields is in the role that industry plays in the translational ecosystem. It could be ascertained that industrial involvement is a crucial step en route to the clinic, although this is unclear from the data presented here. If this is the case, it would be pertinent to identify the circumstances in which industrial involvement is important, for example at what phase(s) in translation.

Regarding the apparently contradictory viewpoints identified, for example, industry funded research as being both more and less innovative, it was hoped that by separating these perspectives into two groups more insight could be gained. However, separating the respondents into either group was challenging due to within-response contradictions (as highlighted in Section 3.2.7), and once completed, when comparing the two groups no features were identified that predisposed one group to one set of experiences. No correlation was observed between academics that experienced industry funding as more or less innovative in terms of clinical versus non-clinical, type of collaboration, or phase of research. However, there are several dimensions that were not encompassed in the survey, such as the size and nature of the department in which the research was situated, the amount of non-industry funding received by the academic, and size of collaborating company, each of which has been found to be important as reported in the literature for other fields (Section 1.2.2.1), and could provide more insight into this apparent contradiction. Furthermore, there is potentially a tension between the finding that industry funds early stage results and the results from the motivations section, which states that industry fund innovative, translational research (as, by its nature, this research tends to be more developed). Taking into account that the data are reflective of the viewpoints of academics, the question is

whether this tension does exist, or whether industry is good at appearing to value things they think scientists value, whilst actually valuing other, perhaps more profitable, ends.

**Study question 1b) What are the barriers preventing or delaying university-industry collaboration?
How do these manifest in terms of perceived disadvantages to collaboration?**

To answer these questions the disadvantages were analysed in conjunction with barriers to cross-validate negative aspects of collaboration. Data for disadvantages were collected as open-ended responses and barriers used a five-point Likert scale; as this study allows for the analysis of deviant cases (Creswell, 2013, Gobo and Mauceri, 2014), themes that appear for only barriers or disadvantages are still considered, and may highlight areas for further exploration.

Overall the results from the open-ended disadvantages section tended to agree with the ranking of barriers to collaboration (Table 3.7). This is particularly true for the themes of 'Difficult to set up' (where both sub-themes of 'Contracts' and 'Navigation' have several clear corresponding barriers) and 'Less well perceived' (where both 'Reduced kudos in academia' and 'Biased, lower quality or corrupt research' were identified in both measures). 'Risks of short-term outlook' were also addressed, as was, to a lesser extent, 'Cultural differences and transparency'.

There were some themes identified in disadvantages that were not corroborated with barriers data. While there is some leeway for differences based on the framing of the question (Littell et al., 1998), some discrepancies were substantial. The 'Loss of control' theme was the most commonly mentioned disadvantage in the questionnaire, yet while aspects of it are discussed in the literature it is not comprehensively covered, and thus was not identified as a barrier in the literature review (Section 1.2.4). The usefulness of using a repeated measure of the negative aspects of collaboration is evident here – it adds validity to themes identified in both sections, while still allowing for nuance in interpretation. For example, while 'Loss of control' is not a barrier in itself, it is a commonly felt disadvantage of collaboration that may well influence

academic's desire to collaborate and benefit that they gain from it. It is not necessarily true that even though a specific barrier and disadvantage do not 'match up', that they are unrelated. Furthermore, while academics were asked to discuss their direct experiences, the concept of a barrier or disadvantage might be a perception rather than a reality. There is an underlying assumption that because the respondents have received industry funding they automatically think industry funding is advantageous. Their perception of a barrier may be based on concerns rather than actual experience.

In order to understand these discrepancies and to better relate disadvantages to barriers, a higher-level conceptualisation of the full dataset could be made. When interrogating the dataset as a whole it was possible to link the negative aspects, positive aspects and strategies together in single units of analysis theoretical framework. This framework encompassed three levels in a micro, meso and macro structure for both industry and academia, as outlined in Section 1.3. In this setting, the micro level represents the individual academic and their experiences, the meso level represents the social and institutional environment of the research, including the perceptions of peers and processes within the university, and the macro level represents the cultural context, including values and attitudes. This structure allows for discrepancies between themes in related questions, while enabling the identification of key areas of overlap. When the barriers and disadvantage from the survey are positioned from this perspective (Table 3.7), factors span both the institutional and cultural levels. These levels are not mutually exclusive, and where there is some overlap or ambiguity (e.g. 'Lack of government funding' could relate to both institutional and cultural barriers) the theme is placed in the category deemed most appropriate in consensus by two researchers.

Table 3.7 Comparison of themes identified in disadvantages and barriers.

Disadvantages	Sub-code	Rank*	Barrier	Agree	Impact
Loss of Control	Overbearing	1	N/A	N/A	Institutional
	Need to adhere to industry goals				
	Less innovative				
	Risks of dependency				
Risks of Short-Term Outlook	Risks of withdrawal	2	Long-term orientation of academic research	47%	Cultural
	Risks of personnel restructuring		Short-term orientation of industry research	62%	
Cultural Differences and Transparency	Decision making	3			Cultural
	Secrecy				
	Lack of understanding		Mutual lack of understanding about expectations and working practices	32%	
	Publishing		Industry restrictions on publication and data sharing	40%	
Difficult to Set up	Contracts	4	Absence of established university procedures for collaboration	25%	Institutional
			Conflicts over intellectual property rights	45%	
			Lengthy contracting process within university	60%	
	Navigation		Limited business development and technology transfer support within university	26%	
			Difficulty finding companies with appropriate profile	34%	
			Lack of government funding to incentivise university-industry collaboration	46%	
On-going bureaucracy	Reporting	5	N/A	N/A	Institutional
	Timelines				
Less Well-Perceived	Reduced kudos in academia	6	Inadequate recognition and incentives within university	50%	Institutional
	Biased, lower quality or corrupt		Ethical issues related to receiving industry funding	21%	
			Perceived conflict of interest from university colleagues	24%	
Funding	Insufficient funding	7	N/A	N/A	Institutional
	Overheads		High costs of academic research	43%	
Unmatched Barriers			Slow speed of academic research	43%	Cultural
			Divergent areas of research in industry and academia	35%	Cultural
			Basic science orientation of academic research	23%	Cultural

*Ranking based on frequency of mention. Unmatched barriers and disadvantages are highlighted in grey.

While this framework illustrates the distribution of the barriers, it does not indicate the significance of each barrier, particularly in terms of the impact it has on the collaboration. For example, while ‘perceived conflict of interest from university colleagues’ and ‘absence of established university procedures for collaboration’ were ranked similarly at 24% and 25% respectively, one may have a greater impact on the ability of the academic to collaborate. Understanding the academic experience of how these barriers impact the initiation and progression of collaboration is important to the design and prioritisation of any strategies to reduce them. While these data have provided an initial scope into the breadth of academic experiences of collaboration in translational medicine, in the next stage more depth will be sought to enable a more complete response to this research question.

Study question 1c) What motivates PIs to collaborate with industry? Do perceived advantages support these motivations?

The motivations and advantages questions were used as repeated measures to cross-validate the positive aspects of collaboration (Littell et al., 1998). However, because both of these questions were open-ended, and as with the comparison of negative aspects from RQ2, this study allows for deviant case analysis (Creswell, 2013, Gobo and Mauceri, 2014), thus if a theme emerges in one section and not another it may remain of interest.

A comparison of the themes identified in responses to motivations and advantages is provided in Table 3.8. The principle advantages mirrored the main motivations for entering into collaboration with industry, with many codes being applied to both of these segments. In particular, the ‘funding’, ‘translation’ and ‘access’ codes, featured prominently in responses to both questions, adding validity to the identification of these themes. Where there is no overlap, these may be tangibly due to the differences in question temporality (i.e. ‘Less on-going bureaucracy’ and ‘Responsive’ arguably can only be known after the collaboration has commenced, and thus cannot be a motivation prior to the collaboration). These motivations and advantages can be categorised

in the same way as for positive aspects identified in the literature (Table 1.5), i.e. in terms of positives for the individual researcher (such as 'Easier', 'Influence' and 'Scientific interest'), for their research program or university (such as 'Funding', 'Access' and 'Collaboration') or for wider society (such as 'Translation' and 'Education'). All of these motivations are intrinsic, i.e. driven by the researcher, and, with the possible exception of 'Leverage', not driven by any external incentives, whether government or university. This is in agreement with the results from Figure 3.10 that rank 'Inadequate incentives and recognition within university' as the third most significant barrier to collaboration. However, it is important to note that the assumption behind the barrier as identified in the literature is a *lack* of incentive, as opposed to the university environment *disincentivising* collaboration. Further investigation is required to understand which of these is the case in Oxford, and whether different strategies are required to resolve them.

Study question 1d) What strategies do academics believe would help initiate/maintain industrial collaboration? How do these strategies address barriers to collaboration?

It is important to consider which barriers each of the strategies address, and the significance of each barrier, so that any implementation could result in the greatest benefit to collaboration. This is particularly true in a situation with limited resources. Here, benefit to collaboration is defined as facilitating the initiation of new collaborations, or enabling the successful implementation and completion of industrial collaboration, either by reducing the amount of time required to do this or by simplifying the process. Table 3.10 indicates the identified strategies in terms of the barriers they could potentially resolve, and whether the resulting impact would be practical, social or cultural.

Table 3.8 Comparison of themes identified in motivations and advantages.

Motivation	Sub-codes	Rank	Sub-codes	Advantage	Rank
Funding	Positive	1	Overheads	Funding	1
	Negative		More funding		
	Personal		Flexibility		
	Neutral				
Translation	Develop work towards application	2		Translation	5
	Patient benefit				
Access	Facilities/ reagents	3	Facilities/ reagents	Access	3
	Knowledge/ expertise		Knowledge/ expertise		
Scientific interest	Interest	4			
	Innovation			Innovation	8
Collaboration	Synergy	5		Collaboration	6
	Complementary skillsets				
Influence	Industry product development	6		Network	9
	Uptake of methods				
	Wider audience				
Leverage		7			
Education	Studentship	8			
	External training				
Unmatched Advantages			Simpler to Initiate	Easier	2
			Less on-going bureaucracy		
			Engaged	Responsive	4
			Responsive		
				Focus	7

*Ranking based on frequency of mention. Unmatched themes are highlighted in grey.

Where strategies addressed issues with the collaboration process, they tended to relate to areas such as navigation and providing initial guidance for academics as to how to collaborate. Where strategies related to cultural or institutional barriers, they tended to describe aims (e.g. increase exchange of personnel between academia and industry) rather than specific strategies (e.g. increase secondments both to and from industry). From Table 3.10, more of the suggested strategies address practical barriers to collaboration than social or cultural barriers. In selecting strategies for further investigation, strategies are evaluated against three criteria depending on whether they: address multiple barriers (at least two), address highly significant barriers (50% or more), or span more than one area of impact. Based on these criteria, the strategies most prudent for investigation would be 'Establish an incentive system', 'Increase exchange of personnel' or 'Streamline standard contracts', as these meet at least two of the criteria.

It is worth noting that the strategies suggested do not address all barriers. In particular, the most significant barrier, "Short term orientation of industry research" is not resolved through any of the barriers suggested, possibly as this barrier is outside of the influence of the university. All barriers that were not targeted by the identified strategies are classified as 'cultural', and due to their intangible nature these barriers may be more difficult to resolve or to measure improvement. Additionally, while these strategies may be effective at resolving these barriers, they were not suggested with this specific goal in mind. It is likely that in order to address the most prevalent or significant barriers strategies other than those proposed may be required.

These strategies do not provide specific guidelines for improving collaboration, but rather suggest desirable aims. For example, while improving incentives or providing recognition are promising avenues for pursuit, the precise incentives or modes of recognition to employ still need to be determined. Thus, while the data collected from this questionnaire have enabled the identification of strategies, the information is not sufficient to prioritise

strategies for investigation, but this is pursued in the next stage of research as described in Chapter 2.

Table 3.10 Comparison of barriers and strategies to improve collaboration and whether their impact would be on a practical, institutional or cultural level.

Strategy	Barrier (%)	Impact
Create a database of all known industrial partners and their interests. AND/OR creating a database of all academics in Oxford and what they're working on.	Difficulty finding companies with appropriate profile (34%)	Practical
Form a group or department within the university with the specific purpose of identifying, facilitating and maintaining partnerships.	- Absence of established university procedures for collaboration (25%) - Limited business development and technology transfer support within university (26%)	Practical
Streamline standard contracts to expedite the formation of partnerships (e.g. MTAs, NDAs, licensing agreements)	- Industry restrictions on publication and data sharing (40%) - Conflicts over intellectual property rights (45%) - Lengthy contracting process within university (60%)	Practical/ Cultural
Host targeted joint events to 'showcase' academic research and enable networking.	Difficulty finding companies with appropriate profile (34%)	Practical
Increase exchange of personnel between academia and industry, by creating joint appointments, 'hot-desking', or encouraging sabbaticals.	- Ethical issues related to receiving industry funding (21%) - Perceived conflict of interest from university colleagues (24%) - Mutual lack of understanding about expectations and working practices (32%)	Institutional / Cultural
Establish an incentive system within the university that recognises or rewards academics for working with industry.	- Lack of government funding to incentivise university-industry collaboration (46%) - Inadequate recognition and incentives within university (50%)	Institutional
Use experienced academics to mentor junior researchers , especially where they have experience of collaborating with the same company.	- Perceived conflict of interest from university colleagues (24%) - Mutual lack of understanding about expectations and working practices (32%)	Institutional /Cultural
Reduce the cost of overheads within the university (either with a government subsidy or by reducing 100% FEC demands)	High costs of academic research (43%)	Practical
Other barriers	- Divergent areas of research in industry and academia (35%) - Long-term orientation of academic research (47%) - Slow speed of academic research (43%) - Basic science orientation of academic research (23%) - Short-term orientation of industry research (62%)	

3.3.5 Summary and next steps

This chapter details the first empirical study on university-industry collaboration in translational research in the United Kingdom. The results highlight how university-industry collaboration is perceived and experienced by University academics involved in translational research, and have the potential to inform research and innovation policies in the United Kingdom and internationally.

This research develops on existing knowledge about the motivations, advantages, disadvantages, and barriers to collaboration, as well as providing novel insight into the types of academia-industry collaboration, the phase of development of the research, and strategies that might be employed to improve it. The aim of this stage of the study was to answer research question 1 and gain a broad insight into the landscape of academia-industry in translational medicine, in terms of the types of collaboration, the phase of development of the research, and the experiences of collaborating academics in terms of their perceptions of motivations, advantages, disadvantages and barriers.

An important strength of this study rests in the methodology – by using mixed methods this research is afforded a degree of validity that cannot be achieved by quantitative or qualitative methods alone. Additionally, due to the use of a well-defined study population, this study is able to access virtually all eligible participants, ensuring that results are meaningful and comprehensive. This study was limited, however, to only those PIs who have received funding from industry, neglecting other interactions that academics can have with industry that do not involve the transfer of funds. It also lacked a comparative control group of PIs who had not received industry funding. Additionally, there are some concerns about the validity and reliability of self-reported data within a long recall period (Lu et al., 2008, Schwarz and Oyserman, 2001). The study would have benefitted from further granularity on the phases of research, especially in the early phase (T0), and the ability to analyse the data using a greater number of factors, such as the number of

collaborations, the total funding amount and the size of the collaborating company. Data collection was prioritised to key areas, however, to comply with anonymity ethics requirements, and so as not to make the survey too laborious (possibly leading to a reduced response rate). Although it could be argued that the generalisation of the results of these data might be limited, as only a single-site was investigated, this is something that could be addressed in the future; this questionnaire could be used as a template to conduct similar studies in other institutions with minimal investment of time and money.

The results of this questionnaire provided a useful roadmap for further analysis. The next chapter explores the use of semi-structured interviews with PIs who have experience of collaboration, to further investigate some of these research questions. This methodology enables the respondents to explore their own experiences of barriers in more depth, and to add granularity to the data and to provide detailed criticisms of the suggested strategies, enabling their development and refinement (Creswell, 2013). Further research questions developed as a result of the analysis described in this chapter include:

- Study question 2a) What role do academics perceive industrial collaboration as playing in the development of their research?
- Study question 2b) In what ways do barriers to collaboration affect PIs at the University of Oxford? Which barriers are perceived to have the greatest impact?
- Study question 2c): Which of the suggested strategies (from Chapter 3) are perceived by academics as being the most useful? How might they be implemented?

Chapter 4: Interviews with Principal Investigators at the University of Oxford

4.1 Introduction

The results outlined in Chapter 3 provided an insight into the landscape of academia industry collaboration in translational medicine, based on data collected by survey from PIs at the University of Oxford. Analysis provided insight into how existing concepts of collaboration are experienced by academics in this field, whilst allowing for the emergence of new themes, and deducing a framework upon which these can be evaluated. In order to increase understanding, a deeper investigation is required into how such process, environmental and cultural factors shape academic experiences of collaboration. Several academics who responded to the survey agreed to participate in semi-structured interviews (see Chapter 2, Section 2.3.3 for full methods). These interviews aimed to add additional detail to the understanding of how perceived barriers may have an impact on the academics' experiences of collaboration, and to develop and refine strategies to address these barriers. These aims were encompassed in the following research questions:

- Study question 2a) What role do academics perceive industrial collaboration as playing in the development of their research?
- Study question 2b) In what ways do barriers to collaboration affect PIs at the University of Oxford? Which barriers are perceived to have the greatest impact?
- Study question 2c) Which of the suggested strategies (from Chapter 3) are perceived by academics as being the most useful? How might they be implemented?

This chapter begins by introducing the structure of the interviews, then presents the results from these interviews in terms of the framework developed in Chapter 3. Finally, the themes are discussed in the context of the research questions (Section 4.3).

4.1.1. Overview of interview process

As described in Section 2.3.3.1, the interview guide comprised four sections:

Section 1: Introduction and background information

This section aimed to provide background information on the academic, including their current role(s), areas of research interest, and career history. Questions asked here were basic to try to relax the PI into the interview and encourage a rapport between interviewer and interviewee.

Section 2: Role of Collaboration

This section aimed to determine the breadth and depth of the PI's experience of industrial collaboration to provide context for the rest of the interview. Information sought in this section included: the number of individual companies the academic collaborated with; the number of collaborations with these companies; company size (i.e. small or large); company type (i.e. Biotech or Big Pharma); the origins, durations and consequences of collaborations, and the extent to which the collaborations were related to the academic's primary research program. It also sought to determine the perceived importance of industrial collaboration in translating biomedical research.

Section 3: Barriers to Collaboration

Here academics were asked to consider the barriers from the questionnaire (Section 3.2.7) and assess their own experiences of these barriers in terms of both the frequency and severity of the barriers.

Section 4: Strategies for Improvement

In this section academics were asked to review the strategies from Section 3.2.8 and provide insight into any they perceive as useful and how they might be implemented.

Example questions for each section are provided in Table 4.1. A complete copy of the interview topic guide can be found in Appendix iv. Additional information on how the topic guide was developed and piloted is described in Section 2.3.3.2.

Table 4.1 Example questions from semi-structured interviews

Section	Sample Question
Introduction and Background Information	Please briefly describe your current role and the focus of your research.
Role of Collaboration	In what ways have you worked with industry in your research? What role has industrial collaboration played in your research? What role does industrial collaboration play in the process of translation?
Barriers to Collaboration	Have you encountered any barriers to collaboration? Please tell me about the most common barrier you've encountered. What was the impact of these barriers on the collaboration? From the survey we were able to rank key barriers to collaboration that were identified in the literature. Looking at the barriers, do you agree with the general order?
Strategies for Improvement	What might have helped facilitate your collaboration? As a part of the survey several strategies were suggested to improve collaboration. Reviewing these strategies, do you think any of these would have been useful to you in your previous interactions? Are there any that you think could be useful to you in the future? In what ways could these strategies be implemented to ensure they are most useful to you?

4.2 Results

4.2.1 Data collection and analysis

Of 169 survey respondents, 38 agreed to be contacted for interview by submitting their email address in a separate online form; and 27 interviews were conducted between February and June 2015. One interview was excluded from the analysis as the interviewee declined to be recorded and the resulting notes were not of equivalent quality to that of the transcripts, especially as it was not possible to return to the original recording to clarify meaning and intonation, as was regularly done for other interviews. An overview of the interviewee recruitment process is shown in Figure 4.1. Of 169 questionnaire respondents, 22% volunteered to be interviewed. Of these volunteers, 68% subsequently participated in interviews. The remaining 32% did not respond to email prompts. Full details of the methodology can be found in Section 2.3.2. The demographics of the interview population were similar to that of the survey respondents (Table 4.2), and both the interview and survey respondent population were generally reflective of the total study population of collaborating academics. Most interviewees had experience of collaboration with more than one company, with five respondents having previously worked in industry, and one respondent soon to leave the University for a full-time position with a pharmaceutical company.

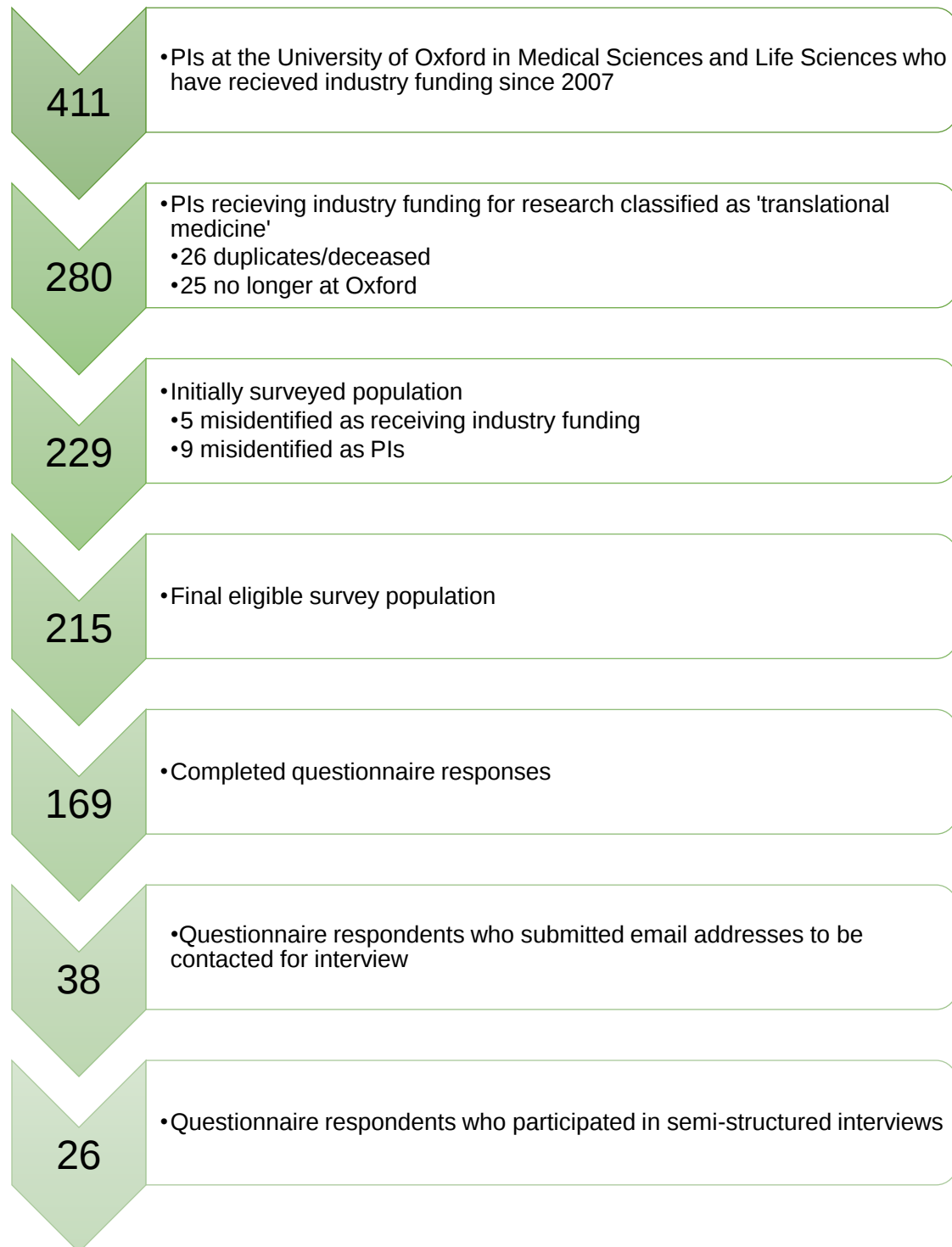


Figure 4.1 Derivation of final interviewees from initial list of PIs obtained from Research Services.

Table 4.2 Demographics of study population, interview respondents and interview participants.

Characteristic	Questionnaire respondents (n=169)	Interview respondents (n=38)	Interview participants (n=26)
Career path			
• Clinician-scientist	76 (45%)	17 (45%)	12 (46%)
• Basic scientist	93 (55%)	21 (55%)	14 (54%)
Professorial title*			
• Yes	135 (80%)	32 (84%)	23 (88%)
• No	34 (20%)	6 (16%)	3 (12%)
Gender			
• Female	37 (22%)	7 (18%)	5 (19%)
• Male	127 (75%)	31 (82%)	21 (81%)
• DNS	5 (3%)	-	-

* Professorial title included Associate Professor and pertained to the respondent at the time of completing the questionnaire. Interview respondents are defined as the group that submitted email address on a separate online form in agreement to be contacted for interview. Response rate from questionnaire respondents to interview respondents was 22%, and from interview respondents to interview participants was 68%.

Analysis of data was based on the framework method. This method is particularly suited for interview data, and enables the reduction of large quantities of data whilst maintaining a strong link with the original data, thus retaining context throughout the iterative analysis process (Gale et al., 2013). See Chapter 2 Section 2.2.2.1 for a full overview of this methodology and Section 2.3.2.4 for details of how it was implemented in this study.

In the results presented in Section 4.2 of this chapter, key themes are initially discussed as they relate to the role of collaboration in translation (Section 4.2.2), then barriers to translation are refined (Section 4.2.3) and analysed (Section 4.2.4), and finally strategies to improve collaboration are discussed (Section 4.2.5). During analysis, the trend of differing experiences for clinical and non-clinical researchers emerged. Where these differences were noted, they have been highlighted in the respective sections and potential reasons for such differences are provided in Section 4.3. Quotes are used where appropriate to illustrate key themes.

4.2.2 The role of industrial collaboration in academic research

A summary of the perception of the role of industry in translation for both clinical and non-clinical academics is provided in Table 4.3. All academics interviewed perceived industrial collaboration as important to translation. This is because industry was seen as having resources and expertise that differ from those in academia. Academics discussed how a both industry assets and academic assets are required for successful translation of innovative technologies. This synergy was seen as one of the key reasons to encourage collaboration. Table 4.4 provides an outline to some of the assets that industry and academia contribute to translation.

Table 4.3 Overview of the role of industrial collaboration for clinical and non-clinical research

Role of collaboration in translation for all academics	
• Industry input into translation was seen as important by all academics because industry were seen as having a complementary skillset to that present in academia. • Interviewees perceived that the translation of novel innovations could only successfully occur when both of these skillsets were combined. • In particular, academics needed industry for two contributions: access to drugs and their surrounding data, and regulatory knowledge. Without these, academics perceive translation as unable to occur. • In addition, working with industry also confers other benefits, including: increased research rigour through sophisticated quality control systems, and increased capacity to conduct experiments and optimise manufacturing processes. • Industry were also seen as important to translation for the 'funding' they provide, though this funding was utilised differently for clinical and non-clinical research.	
Role of industry funding for Non-clinical academics	Role of industry funding for Clinical academics
• Industry perceived as 'enabling' – funding more innovative, high-risk research that is unappealing to research councils.	• Industry seen as 'safety net' – funding less challenging research, providing a cash cow to conduct more interesting research.

Of the industrial contributors, two factors were seen as crucial to the ability of academics to translate their research:

- Industry control access to drugs and the data surrounding them
- Industry have regulatory knowledge that is difficult to obtain otherwise and generally absent in academia

The clear majority of new drug approvals are industry-led, and access to industry drugs enables academics to conduct relevant research. Therefore, if academics are investigating any aspect of a drug, for example mechanisms of action, or new indications, or subsets of patients, they need to work with industry to access data. Furthermore, by working with academics industry gain access to animal models and years of expertise on one subject. However, in order to develop a therapeutic, academics require a different knowledge base in order to address the regulatory burden of translation.

As discussed in Section 1.1, developing a product from proof-of-concept through to marketing authorisation requires a wide range of expertise, in addition to substantial amounts of funding, time and resources. By collaborating with industry, academics can harness existing expertise instead of investing significant time and effort acquiring it themselves. Furthermore, extensive industry experience of pre-clinical and clinical development can be applied to accelerate the rate of translation beyond what is possible in academia alone. Industrial collaboration was seen as providing a rapid path to regulatory approval.

Table 4.4 List of assets both academia and industry bring to collaborations with the goal of translation

Industrial contributors to translation	Academic contributors to translation
Drug compounds Data about drug compounds Regulatory knowledge Prior experience of translation Financial resources Processing capacity	Extensive subject-specific expertise Unique experimental tools e.g. animal models Access to patients Reputational value

Academics felt that the capacity or ‘might’ available within industry increased the likelihood of successful translation. Academics could access teams of industrial researchers to, for example, simplify manufacturing methods or perform large toxicology studies, which they may have been unable to perform in academia due to the high costs associated.

Furthermore, academics believed that industrial involvement improves the rigour or quality of the research. Industrial quality control systems were seen to improve the reliability and reproducibility of results, ultimately resulting in data that is robust and more likely to be true. This contradicts with some of the literature reviewed in Chapter 1 where industry research was perceived as more likely to be biased or untrustworthy. Yet in this case, through collaboration with industry, academics felt able to conduct translational work more efficiently, to a higher standard of quality, and that ultimately is more likely to succeed. Academics also highlighted the role that industry funding plays in sustaining their research. However, regarding this funding, differences emerged in the experiences of clinical and non-clinical researchers.

4.2.2.1 Non-clinical researchers

Non-clinical researchers perceived industry as providing funding for more innovative, research. Specifically, industry was perceived as funding research that would be too “high risk” or out of fashion with other funding bodies. Several academics discussed being unable to secure funding from charities or Research Councils because translational research falls through a ‘gap’ in the remits of these groups. Interviewees described Research Councils as less willing to fund first-in-class or novel interventions because not enough was known about their efficacy and side effects, instead preferring to fund ‘safe’ research where the outcomes are ‘all but certain’. Indeed, academics described having

already done much of the work for a Charity or Research Council grant by the time they apply for funding.

Translational research was believed to be unappealing to charities and Research Councils for three key reasons. Firstly, due to the use of high-quality reagents translational research tends to be more expensive than basic research. Secondly, translational research may concern proof-of-concept or optimisation studies, which are less amenable to publication than basic research studies. Thirdly, because of the rigour of assessment required to bring an intervention to clinical trials, the likelihood of failure is higher than for basic research studies. These characteristics of translational research may represent it as an unattractive option for Research Councils, which have a duty to protect and deliver maximum value from public funds, and may choose, for example, to fund several basic science projects over one translational project. Furthermore, even in cases where a translational project is funded, due to the additional quality and regulatory requirements, the costs associated with translational research increase the more developed a given product (DiMasi et al., 2016). Thus, beyond a certain point in the process of translation, irrespective of whether Research Councils are willing to fund a project, the sums of money required to continue the research were seen as not obtainable within academia. Therefore, in order to pursue this riskier translational research, academics can either form a company and seek funding from business angels or venture capitalists, or seek funds from industry. In this way, industry enables non-clinical academic researchers to conduct innovative, high-risk translational research, that may otherwise be unable to occur. The fact that academics perceived Research Councils as funding less innovative research than industry is a surprising finding, and questions whether the existing remit of Research Councils are best serving academics.

4.2.2.2 Clinical researchers

In contrast to non-clinical academics, many clinical researchers perceived industry-funded projects as less innovative than projects funded by Research Councils. In some cases, industrial research was characterised as ‘boring’, with companies unwilling to run counter to the current ‘dogma’ of what other pharmaceutical companies are pursuing. One clinical academic noted the impact of this on his group, stating that because industry-funded research is less novel, the resulting data is hard to publish, or publish in a well-respected journal, discouraging potential post-doc from working on the project.

In a similar way to non-clinical research, industry were also seen as ‘enabling’ research that would not otherwise be funded, but for different reasons. Clinical academics discussed how the research is routine or bland, but often well-funded, which may enable the academic to subsequently conduct other, more interesting research. Additionally, where Research Councils and Charities were seen to fund research on diseases with high mortality rates (especially charities, where sufferers may leave donations in their will), industry were willing to fund projects that concerned diseases from lower mortality rates, enabling a greater breadth of research to be conducted on what may otherwise be more neglected disease areas.

However, while providing an additional source of research funding was a key role of industry in translational research in general, the more pressing reason for clinical researchers was to gain access to products, data and expertise. In particular, clinical academics highlighted the importance of industry in providing drugs, enabling academics to perform the most cutting-edge research, and thus secure other non industry grants.

Finally, it is of note that *researching* clinical academics (those included in this study) perceived that data generated in collaboration with industry to be ‘gold plated’ – very likely to be true. This is because industry have the money and equipment to be able to

execute experiments to the highest standard. Additionally, because the financial success of a company may depend on the strength of its science, the future of the company may depend on results being true. This perception of industry funded data as robust contradicts the literature in which the many non-researching clinicians believe that industry generated data ‘cannot be trusted’ (Kesselheim et al., 2012). This is perhaps indicative of a difference in experience, and subsequently perception, of the quality of academic research amongst researching and non-researching clinicians. Researching clinicians have a high regard for the robustness of industry-generated data as opposed to academic-generated data. Non-researching clinicians regard industry research as biased, and academic research as impartial.

4.2.3 Barriers to academia-industry collaboration

The interviews enabled a more critical review of the barriers identified in the literature review in Chapter 1 and then evaluated in the survey in Chapter 3. The original barriers have been refined and presented in Table 4.5. In some cases several original barriers are addressed by one or more refined barriers. The conflicting nature of industry funded research for clinical and non-clinical academics (as either innovative or pedestrian) contributed to some differences in the experience of collaboration for these two groups of researchers, and these are highlighted in the table.

Table 4.5 Original barriers and refined barriers to collaboration.

Original Barrier(s)	Refined Barrier (section discussed)	Notes
Short-term orientation of industry research	1. Industry change focus and 'drop' projects	Industry tend to shift their research focus and 'drop' projects due to changes in hierarchy, market trends or restructuring.
	2. High turnover of personnel in industry	People in industry frequently change jobs so the point of contact for the academic changes and they need to establish new relationships.
Lengthy contracting process within university Conflicts over intellectual property rights High costs of academic research	3. Lengthy contract negotiations, especially due to disagreements over IP and FEC	Delays to contracting process seen to come from both academia and industry, and seen as a substantial barrier to collaboration. Disagreement over IP considered a contributing cause to lengthy contract negotiations, in particular because the university is "too greedy". Conducting research in academia is not expensive in itself, but overheads are sometimes seen as too high and as a barrier to collaboration.
Inadequate recognition and incentives within university Perceived conflict of interest from university colleagues	4. Inadequate recognition and incentives for collaboration	There is a lack of incentives and recognition both within the university and externally.
	5. Less well perceived by university, committees and the public (CLINICAL)	Clinical academics experienced negative perceptions from colleagues of their industry-funded research. Industry-funded research was seen as biased or a conflict of interest. This was much less common for non-clinical research.
Industry restrictions on publication and data sharing	6. Industry restrictions on publication and data sharing (NON-CLINICAL)	Industry restrict or delay publication for non-clinical researchers
	7. Industry-funded research more difficult to publish (CLINICAL)	Industry funded clinical research is 1) less novel, and 2) less well perceived, which makes it difficult for clinical researchers to publish in good journals.
Difficulty finding companies with appropriate profile	8. Navigation issues, finding the right person within a company	Ambiguity concerning industrial hierarchy means that academics struggle to find appropriate contacts within a company with which to establish a collaboration
Mutual lack of understanding about expectations and working practices	9. Industrial restrictions on time and focus limit academic freedom	Conflicts arise due to different working styles. Industry are milestone driven and push to deliver the specific aims of a project as quickly as possible. Academic research is more driven to explore the main and arising research questions, and so tends to be less focused and slower to reach endpoint.

Limited business development and technology transfer support within university	10. Lack of guidance on collaboration	Academics reported damaging relationships through silly mistakes that could have been avoided if they had a better understanding of what to expect from industry.
Absence of established university procedures for collaboration	11. University allows patents to lapse too early	OUI and BD (where known) were seen to be adequate in their tech transfer support, however the lapsing of patents after a year if partners can't be found negatively affected both academics ability to find partners and to translate their own research
Not widely considered barriers		
Basic science orientation of academic research		Industry seen to fund basic non-clinical research.
Divergent areas of research in industry and academia		Areas of overlap commonly found
Lack of government funding to incentivise university-industry collaboration		Lack of short-term funding generally not seen to be an issue.
Ethical issues related to receiving industry funding		Industry funding can be ethically received
Long-term orientation of academic research		The long term orientation of academic research isn't a barrier, but can conflict with industrial culture of staff turnover and propensity for sudden change.
Slow speed of academic research		Academics being too slow is not generally seen as an issue, more to do with different speeds of academic and industry research.

Original barriers are grouped together where they are addressed by a similar group of refined barriers.

The barriers in this table have been refined to reflect tangible and specific issues encountered during the process of collaboration (i.e. “short term orientation on industry research” has been refined to “Industry change focus and ‘drop’ projects”). Each of these barriers is briefly discussed, before being analysed within the cultural context of academic and industry settings in Section 4.2.4.

1. Industry change focus and ‘drop’ projects

‘Short-term orientation of industry research’ was the most commonly identified barrier, selected by 62% of the survey population (Section 3.2.8). When exploring this theme during interviews and analysis, academics tended to experience this limited time horizon through industry ‘dropping’ projects, or suddenly withdrawing funds, resulting from changes in the focus or direction of industrial research.

Sudden changes in the focus or direction of industrial research, causing projects to be ‘dropped’, were mentioned by 24 academics. This led to the perception of industry funding as uncertain or unstable. There was an understanding that industry tend to frequently change their research focus due to several internal and external factors, such as changes in the research interests of competitor companies, changes in personnel, company restructuring, the geopolitical climate and regulatory decisions. Therefore, even if an academic collaboration was progressing successfully, funding could be withdrawn if a research area was no longer seen as favourable by industry. This contributes to the perception of industry funding as uncertain, and highlights a powerlessness on the part of the academic: irrespective of whether they are fulfilling their part of the agreement, industry can withdraw funds at will, generally terminating the project.

2. High turnover of personnel in industry

The high turnover of staff in industry was mentioned as a barrier to collaboration by 23 out of 26 interviewees. It was described as occurring both as contacts moved company or were promoted, and as a result of other internal and external factors as discussed for the previous barrier. High turnover of personnel was experienced as disruptive because:

- Academics felt that their industry contact was likely to change roles within or between projects and therefore was less invested in the project
- changes to staff were associated with shifting attitudes or priorities within a company, e.g. a new CSO may change the company focus away from the academic's project
- academic may have to expend significant effort to educate the new point of contact on the area of research and the progress already made
- changes in personnel resulted in the disruption of on-going negotiations, requiring a complete renegotiation of contracts, delaying progress

The impact of such high staff turnover is significant because it disrupts the formation of long term relationships with the company, which many academics described as the basis of successful collaboration.

3. Lengthy contract negotiations, especially due to disagreements over IP and FEC

Contract negotiations were highlighted as one of the most significant barriers to collaboration in the questionnaire, with 60% of respondents identifying it as an issue. During interviews, it was found that there was a general uncertainty about the contracting process, with academics describing Research Services (RS), the group responsible for negotiating contracts, as a “black box” where contracts are sent and not returned for long periods of time, sometimes for years. Many academics felt removed from the process, and were frustrated by a lack of communication from RS about delays and the key issues with

the contracts. This prevented them both from being able to plan for delays, and from improving the contracting process in their future collaborations. The delay caused by the contracting process sometimes resulted in lost funding, due to industry frustration with the protracted contract discussions, or because over the course of the negotiations industrial focus shifts away from the original research area.

Where academics were more aware of the process, all but two interviewees felt that RS were obstructive rather than supportive in their research objectives. Academics saw RS as disrupting their relationships with industry pushing companies away over issues that were of low importance to the academic. Many academics described instances where they had agreed to project terms with industry which are subsequently refused and renegotiated by RS. From an initial position that both the academic and company are happy with, RS are seen as 'greedy' and trying to gain unfair access to, for example, royalties or IP, deterring the company from working with the university, or that academic in the future. Thus, due to both delays and disruptions to relationships, academics saw RS as preventing good research from being conducted over 'pointless' negotiations.

The main sources of contention during negotiation were identified as overheads and IP. Overheads are the costs associated with conducting a research project in addition to specific costs of the research itself. Universities calculate the cost to its institution of conducting research in terms of full economic costing or FEC, defined as 'a price, which, if recovered across an organisation's full programme, would recover the total cost (direct, indirect and total overhead) including an adequate investment in the organisation's infrastructure' (Support, 2014). FEC is more fully explained in Section 1.2.2.3.1 of this thesis. Many universities, including the University of Oxford, expect industry to pay 100% (or thereabout) of the FEC associated with a project. While academics were supportive of charging 100% FEC to large pharmaceutical companies, in circumstances where the company is small, or the academic has initiated the collaboration, it was described as

‘scaring off’ companies and ‘taxing what you actually want to happen’. Academics felt that charging ‘unreasonably high’ FEC felt exploitative and made the university seem out of touch, seeing industry as a ‘cash cow’ instead of a genuine partner in collaboration.

The second negotiating ‘sticking point’ was the ownership of intellectual property (IP). As with overheads, protecting IP was seen reasonable and important, yet often pursued to the point where it damaged or prevented collaboration. The University was also described as being “too greedy” regarding its approach to forward-looking IP, resulting in lost funding and collaborations. This was seen as especially damaging as industry are often more likely than academics to progress a project through to the clinic, and high levels of IP ownership by the university were seen as discouraging them from doing so.

While academics could see the potential benefit of contracts and negotiating hard on IP and overheads, the effects that they sometimes had – missed funding opportunities, damaged relationships and lost productivity through reduced time or late access to tools – were often seen as too high a price to pay, and counterproductive to collaboration and research. As outlined in Section 4.2.2, academics see industry as vital to translation, and one academic questioned whether the university should be charging industry higher overheads than Research Councils and charities, stating that the university *needs* to work with industry to access drugs, knowledge and data, whereas Research Councils provide only funding.

4. Inadequate recognition and incentives for collaboration

Many academics highlighted a change in attitudes within the university, where working with industry was previously seen as ‘dirty’, to an environment that encourages or even requires industrial involvement. However, despite this shift in attitudes, none of the 26 academics interviewed felt that the university recognised their industrial collaborations.

Indeed, one academic stated that involvement in this project is the first time in 25 years that she has been asked about her industrial collaborations.

Academics emphasised the importance of industrial collaboration for translation, and advocated for collaboration to be recognised within academia to the same extent as teaching or participation on committees. PIs suggested that the recognition for industrial research had not improved with more favourable attitudes because often the outcomes of research collaborations differ from conventional academic goals. For example, through a translational research project an academic may drive the approval of a new drug or conduct a new clinical trial, yet the project may not produce a high impact publication for several years. Academics wished to ensure that a more diverse range of research outputs were recognised.

5. Less well perceived by university, committees and the public (CLINICAL)

While no academic felt recognised for their industrial collaboration, there were differences in how such research was perceived for clinical and non-clinical academics.

Only two non-clinical academics mentioned experiencing negative perceptions from their colleagues. However, these negative perceptions were linked to a 'snobbishness' regarding the intellectual merit of basic vs. applied research. It appears that perceptions amongst the colleagues are driven by how applicable the research is rather than the funding source. Thus, industry funded research may be less well perceived not because of industry, but because industry-funded projects are more likely to be applied.

Conversely, the majority of clinical academics reported experiencing negative perception from colleagues, journals, grants committees and the public. For clinical academics, industrial collaboration was negatively regarded because 1) the academic was seen as not

talented enough to gain 'legitimate' funding from Research Councils or charities, or 2) industry involvement was seen to bias and corrupt research. In clinical research working *with* industry was seen as working *for* industry, conducting industry-designed trials which favour a specific company's product or commercial interest.

These perceptions made it more difficult for academics who had worked with industry to gain credit for their work, reducing their ability to gain non-industry grants, and restricting their ability to work in the public sector, where PIs need to be completely 'clean' of industry involvement.

The basis of the difference in perception between non-clinical and clinical research, was ascribed to differences in coverage by the scientific and lay press, and the direct impact of clinical research on patients.

6. Industry restrictions on publication and data sharing (NON-CLINICAL)

Publications are the basis for many assessments of academic progress, including the allocation of grants from funding bodies (Partha and David, 1994). Thus, not being able to publish data in well-respected journals can affect the credibility of the academic and their ability to conduct research, attract top research staff, and secure non-industry grant funding (academic culture is commonly described using the motto 'publish or perish'). While all PIs interviewed in this study indicated that collaborating with industry impacted their ability to publish, this impact was experienced in different ways for clinical and non-clinical academics.

The non-clinical researchers interviewed described feeling constrained in their ability to publish data generated from industry-funded projects. In this case, the academics wish to publish but the company blocks or delays publication so that it can first evaluate any potential intellectual property. Academics described this blockage or delay as a key challenge of collaboration, and some more senior interviewees described how they would not have been able to collaborate as early-career researchers as this restriction on publication would have hampered their career.

7. Industry-funded research more difficult to publish (CLINICAL)

Conversely, clinical academics did not feel that industry delayed or restricted their ability to publish data from industry-funded projects, with many highlighting how this had never been an issue for them. However, as discussed in Section 4.2.2, industry-funded clinical research tends to be less innovative than non-industry funded clinical research, making it harder to publish as journals seek more ground-breaking papers. Furthermore, due to the mistrust of industry in clinical academia some journals refuse to publish studies funded by industry, and where publication is achieved, the data (and paper) may not be regarded as highly.

8. Navigation issues, finding the right person within a company

While there was one example where finding a company with an appropriate profile was a key barrier (for a researcher who worked in rare diseases, where the chances of a company having a pre-existing interest in a particular disease is low), most navigation issues occurred at a level where the company had been identified, but it was difficult to find the right person to talk to within it. This is because generally academics wanted to

work with specific drugs, therefore identifying the company was straightforward, though identifying a suitable entry point was not.

Academics discussed wasting time talking to the 'wrong' people, who were unable to make decisions and award funding but would 'string' them along in order to prevent them collaborating with competitor companies. This was more of an issue in larger companies than smaller ones. The 'right' person was described as someone who could make the required decision, whether for a small research grant or a wider institutional collaboration. Identifying the effective level of seniority of a collaborator, however, seemed to be confounded by the lack of consistency or ambiguity surrounding industry titles and job roles.

9. Industrial restrictions on time and focus limit academic freedom

One barrier to collaboration highlighted by academics was industrial restrictions on academic freedom and working style. When working with industry academics were expected to adhere to strict milestones and deliver an answer to a set research question as quickly as possible. Academics were unable to explore avenues outside of the agreed research question, and felt constrained by the rigidity of industry timelines and the need to meet milestones. Academics described how it sometimes seemed as if industry were treating the university as a contract research organisation, rather than a partner in collaboration. This not only made the research less fulfilling for the academic, as they were unable to gain a deeper understanding of the research problem, but also was seen as bad for industry, as the company misses out on much of the value of working with academics by constraining their creativity.

This constraint in terms of time and milestones was experienced by both clinical and non-clinical researchers. As for previous barriers, there was a difference in the way that

industry managed collaborations for these different types of research. Non-clinical academics, while restricted by time, generally described industry as quite 'light touch' in their management of the collaboration, often letting the academic 'get on' with the research. Their academic freedom was primarily constrained by time. Conversely, clinical academics described the industrial presence as overbearing and often a point of contention in collaboration. Academics discussed how they had to stick to industrial research designs, and were frequently monitored by the partner company. For clinical academics, industry wanted much more control over the design and implementation of the research.

10. Lack of guidance on collaboration

All interviewees discussed the 'learning curve' that they had to go through in understanding how to work with industry. Many of the barriers discussed above, including restrictions on time, the prospect of projects being suddenly dropped and delays caused by contract negotiations were seen as manageable if the academic knew to expect them. Academics described a process of 'struggling through alone' and making common mistakes that could have been avoided if they had been provided with any guidance or insight into what collaboration with industry entails. This lack of knowledge transfer within the university was said to have amplified the effects of cultural differences between academia and industry, and resulted in negative experiences of collaboration for both the academic and the company.

Additionally, as mentioned in the contracts section, some academics described how they had reached an agreement with industry that then had to be completely renegotiated once Research Services had been engaged, damaging their relationship with the company because of mismanaged expectations. Thus, academics did not seem to understand which

factors were important to university administration during negotiations, and those on which they could compromise. Nor did they have a way of gauging what was reasonable to ask for from industry, for example, in terms of publication restrictions.

11. University allows patents to lapse too early

The filing and maintenance of IP within the University of Oxford is conducted by its Technology Transfer Office (TTO), Oxford University Innovation Ltd (OUI). OUI is a limited company which aims to deliver returns to the university through the commercialisation of its research, generally by protecting university inventions through patents which are then licensed or sold to external partners. It has a limited budget with which to file and maintain these patents. In terms of costs incurred, there is an initial fee incurred when filing patents, then further payments as the patent passes certain milestones. The longer a patent is maintained the more expensive it is. Because of these escalating costs, OUI aims to find a partner to licence an invention to as quickly as possible, so that these fees can be passed on. If no partner can be found, the patent is evaluated and may be allowed to 'lapse', forfeiting any protection of the IP.

Where inventions are no longer patent protected, market exclusivity is not guaranteed and there may be little commercial drive for further development. Academics described how this hampered their ability to translate their research, leaving the resulting innovation vulnerable to competition and of limited commercial viability.

4.2.4 Analysis of barriers

These barriers are encountered by academics (or not, as the case may be) during the process of collaboration. These barriers could be said to be ‘artefacts’ or manifestations of a wider difference in cultural values between academia and industry (Schein and Schein, 2016). By using the framework discussed at the end of Chapter 3, it is possible to propose potential larger cultural and structural systems underlying these different barriers.

4.2.4.1 Factors underlying key barriers

Organisational culture has been defined as ‘A pattern of shared basic assumptions learned by a group as it solved its problems of external adaptation and internal integration... a pattern or system of beliefs, values and behavioural norms’ (Schein and Schein, 2016). This analysis examines survey and interview data to identify how differences in culture between these academics and their industrial collaborators may contribute to these barriers. In this study, an analysis of culture extends beyond individual organisations and towards a broader consideration of industrial culture as a whole, in relation to the culture within academia.

The barriers previously described could be assembled into loose groups depending on whether they stem from differences between the way academia and industry value three factors: time, money and data-sharing. The different ways in which these factors are regarded in academia and industry has resulted in two distinct approaches to research in these settings. Thus, when these two groups collaborate there can be a tension between the two styles of working. Additionally, some barriers can be linked to potential differences in the clinical and non-clinical sub-cultures within academia. Finally, some barriers seem to be due to process inefficiencies within the university or industry, these are described as institutional features. While these categories describe various aspects of

barriers, it is worth noting that due to the complexity the barriers and the range and nuance with which they are experienced, there is some overlap between barriers and not all of them fit perfectly within the framework. Nonetheless, the framework is a useful tool with which to understand the source and experiences of these barriers. Figure 4.2. provides a schematic of this framework, and Table 4.6 lists the cultural or institutional features that relate to each barrier.

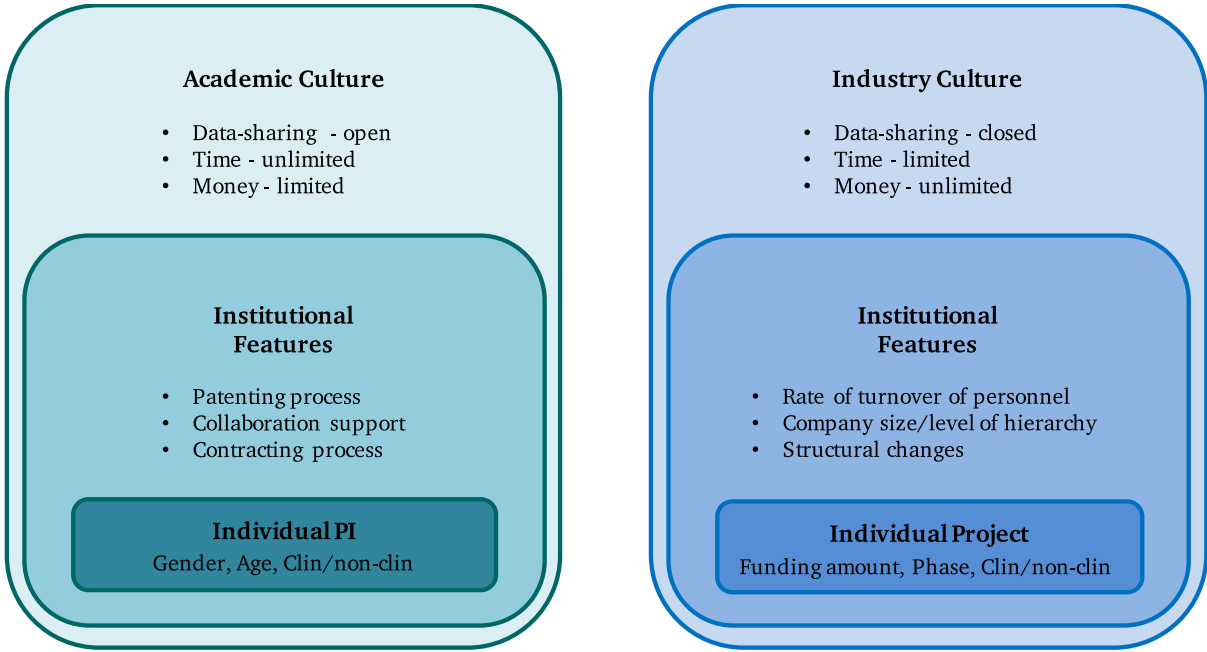


Figure 4.2 Key cultural and institutional factors

Table 4.6 List of barriers and suggested contributing cultural or structural factors

Refined Barrier	Contributing cultural factor
1. Industry change focus and 'drop' projects	Differences in 'time culture'
2. High turnover of personnel in industry	Differences in 'time culture'
3. Lengthy contract negotiations, especially due to disagreements over IP and FEC	Differences in 'data sharing' culture' Differences in 'money culture'
4. Inadequate recognition and incentives for collaboration	Institutional feature of university
5. Less well perceived by university, committees and the public (CLINICAL)	Clinical vs non-clinical sub-cultures Differences in 'data sharing' culture'
6. Industry restrictions on publication and data sharing (NON-CLINICAL)	Differences in 'data sharing' culture' Clinical vs non-clinical sub-cultures
7. Industry-funded research more difficult to publish (CLINICAL)	Clinical vs non-clinical sub-cultures
8. Navigation issues, finding the right person within a company	Institutional feature of industry
9. Industrial restrictions on time and focus limit academic freedom	Differences in 'time culture' Differences in 'money culture' Clinical vs non-clinical sub-cultures
10. Lack of guidance on collaboration	Institutional feature of university
11. University allows patents to lapse too early	Institutional feature of university

4.2.4.1.1 Academic vs industry cultures of ‘data-sharing’

Academics and companies value data-sharing and disclosure in arguably opposite ways. Publishing is fundamental to career progression in academia, and while academics may be cautious with sharing new data, ultimately the aim of academic research is to disseminate the findings. Conversely, in industry much of the value of an innovation comes from keeping it confidential for as long as possible, until it can be protected. The role of patents is particularly interesting, as the number and strength of patents influences the overall worth of a company. In the UK, publishing a paper on an invention is a novelty-destroying disclosure, precluding that invention from being patented.

It is worth noting that this paradigm is changing. Industry are increasingly beginning to publish in academic journals with non-commercially relevant data, and academics are increasingly being made to evaluate the IP potential of their research. Despite this, it seems that in the current drug development system the drivers of patenting of publish are difficult to reconcile, and it is hard for either group to compromise on a factor that is so fundamental to their purpose. Thus, the push-pull between these two aims, of publishing vs patenting, can be the source of tension in collaboration, where neither side is willing to concede on their key priorities, leading to the barriers identified above including lengthy contract negotiations, and where compromises have been reached, industry restrictions on publications and data sharing. It is also worth noting that in preliminary discussions with industry, members highlighted an academic disregard for agreed terms surrounding publication delay.

4.2.4.1.2 Academic vs industry cultures of ‘time’

Time is important for industry due to the limited life of patents. Patents typically last for 20 years from the date of filing, and prices for drugs can fall dramatically once a drug is

off-patent (Frank and Salkever, 1997). Therefore, there is a need to progress quickly through clinical trials in order to maximise the remaining patent-life post-approval. Because of the market monopoly granted by a patent, any additional patent-life post-approval can result in substantial profits for the company. This results in a working style in industry that is linear – the fastest route to the yes/no answer.

While it is not entirely true to say that time is unlimited in academia, it is experienced as serving a very different purpose. Academics tend to focus on one topic for the duration of their careers, and time is valued as a necessary component of good research. Many academics interviewed highlighted how true originality comes from thinking about something for a long period of time. They seek to produce an original publication based on clever, well thought out experiments, and to enhance their understanding as much as possible by investigating new research questions that might arise out of data. Thus, academic working styles could be described as non-linear.

During collaborations, the clash of these different working styles leads to academics (in particular, clinical academics) feeling ‘restricted’ by industry, unable to explore the topic and restricting their understanding of the area.

Differences in time culture between academia and industry are also related to the rate of change within institutions. As stated previously, industry are susceptible to the influence of external market forces, and may need to change their research strategy quickly and with short notice. Furthermore, industry is more prone to restructuring and institutional changes such as mergers and acquisitions, which may further impact the direction of the research. This results in both a high turnover of personnel, as people move around and between companies, and in the propensity to change focus and ‘drop’ projects that are no longer commercially attractive or justifiable.

The sensitivity of industry decision-making processes to external market influences has several practical implications for a collaborating academic.

- Firstly, when industry is interested in a field of research it is important that contracts are negotiated and signed as quickly as possible, before a shift in industrial focus occurs. Indeed, frustration over delays in the contracting process were a key frustration for academics.
- The need to be able to withdraw funds at short notice means industry tend to pursue short term contracts, for example, one year contracts with options to renew. These short contracts create uncertainty around job security, making it difficult for academics to attract the best staff to their research groups.
- Industry tend to work at a faster pace than in academia, and may implement milestones or assessment structures that some academics described as restrictive.

It is worth noting that some academics also highlighted comparable disadvantages for non-industry funding, including short-contract lengths from charities and Research Councils, and increasingly demanding reporting and milestones. This is in addition to academics highlighting Research Councils as risk averse and unwilling to fund translational research, a key and surprising finding.

4.2.4.1.3 Academic vs industry cultures of ‘money’

The ways in which academia and industry value money seems to differ in two key ways.

Firstly, differences in the availability of money lead to differences in working styles between academia and industry. Most larger companies are able to direct substantial resources to a project when it is the topic of focus, and drive a project forward to enable

a go/no go decision to be made as quickly as possible. Conversely, academics tend to work within a relatively frugal environment where they must justify the use of public funds. In this case, academics may seek to get as much value out of a given funding amount as possible, performing many, more informative experiments than those needed to obtain a specific answer. This difference also contributes to academic experiences of being 'restricted' by industry during collaborations, as they may need to substantially modify their working style, to their perceived detriment of the project.

Secondly, differences in the way that academia and industry value money lead to conflicting decision-making processes – based around profitability in industry, and scientific merit in academia.

Academics discussed the value of being able to determine their research topic irrespective of external pressures. The fact that personnel within industry do not have this freedom was a source of sympathy from academics for their industrial counterparts, and a key differentiation between the two working environments. This cultural difference is striking, and the focus on money over science appears to conflict with a key academic value, and may be a cause of the negative perception of industry by public bodies. As one academic states:

P10: "I feel quite sorry for my colleagues in industry, because they may have an absolute passion for something that they are working on and then they're told that they've got to reinvent themselves as a neuroscientist tomorrow because that division's gone... I'd find it really really hard to work in industry, because it matters to me too much what the science is that I'm working on... An academic lab could beaver away at something, sometimes with more money, sometimes with less, and sometimes it's scrapping by its fingertips. But it could still carry on studying that area..."

Furthermore, if a research topic isn't an industry priority then it can be very difficult to get it supported. This is especially true for fields with an unfavourable patent landscape. However, when an area of research is an industry priority the resources available can be far beyond what is accessible in academia. Several academics described taking advantage of industry 'appetite' in their field to gain substantial funding and obtain new research equipment.

Finally, where disagreements over paying overheads occur, this barrier was seen as due to the university demanding unrealistic sums of money. In this case, there is a difference in the position of the academic and their institution.

4.2.4.1.4 Clinical vs non-clinical sub-cultures

Differences between the cultural experiences of clinical and non-clinical academics emerged from analysis of the interview data in a way that was not identified from the survey outlined in Chapter 3. This may be due to two distinguishing features – differences in the sub-cultures of clinical and non-clinical academic research, and differences in industry's aims for the collaboration.

Differing sub-cultures or 'tribes and territories' between academic disciplines have been described in the literature (Becher and Trowler, 2001). Clinical and non-clinical academics have different journals, metrics of success, and necessarily different levels of patient interaction. Consequently, a contributing factor to the diversity of these experiences may be because the nature of interactions with industry differ for these two groups. While delivering shareholder value remains an important factor for industry regardless of the type of research, as indicated by similar experiences for the turnover of staff and propensity for sudden changes in industry decisions, the way in which a company sets out to achieve profit may differ for clinical and non-clinical research.

Industry may pursue non-clinical projects in order to identify new targets or increase their understanding of a mechanism or disease area. On the other hand, industry may pursue clinical research in order to promote familiarity and use of their existing products. These different aims necessitate different approaches towards confidentiality and IP for clinical and non-clinical research.

For non-clinical work, industry were seen to fund more risky or innovative research, academics are given more freedom to allow for this, and as the research is more novel it is more likely to generate arising IP. Therefore, industry may be more concerned with protecting IP in these projects, and so industrial attitudes towards confidentiality and publication restriction are felt to be more aggressive. Because of this, peer perceptions of industrial collaboration are generally neutral, unless academics are seen to be actively detracting from the university, for example by not paying sufficient overheads.

Conversely, for clinical research much of the IP has already been filed, and the generation of new IP less common. Instead, exposure of the research and the drug becomes increasingly more important, and industry may fund late phase trials to facilitate this. However, because of the susceptibility of industry to negative press, industry may be very prescriptive and controlling of the study, thus restricting academic freedom and innovation, or leading to the use of persuasive techniques such as 'key opinion leaders'. The resulting peer perception is generally negative; as an industrial presence may be indicative of a lack of academic integrity or skill. Additionally, the low levels of academic input means that industry studies were often seen as 'boring' by academics, however the high levels of funding they bring in could be used to fund other, more interesting research projects.

A model was developed to link industry aims to clinical and non-clinical experiences (Figure 4.3). In this model, the differences stem from industry goals of either developing new drugs (i.e. with non-clinical academics), or by finding ways to increase the profile

and sales of existing drugs or drugs which are approaching regulatory approval (i.e. with clinical academics). The postulation then, is that while the incentives and drivers within industry remain constant, the purposes for which they collaborate with clinical and non-clinical academic research differ, which manifests as different cultural and environmental experiences for these two groups. Whilst it is difficult to draw firm conclusions around this without the input of members of industry, if correct this may inform the guidance provided to collaborating academics, depending on the type of research they are pursuing.

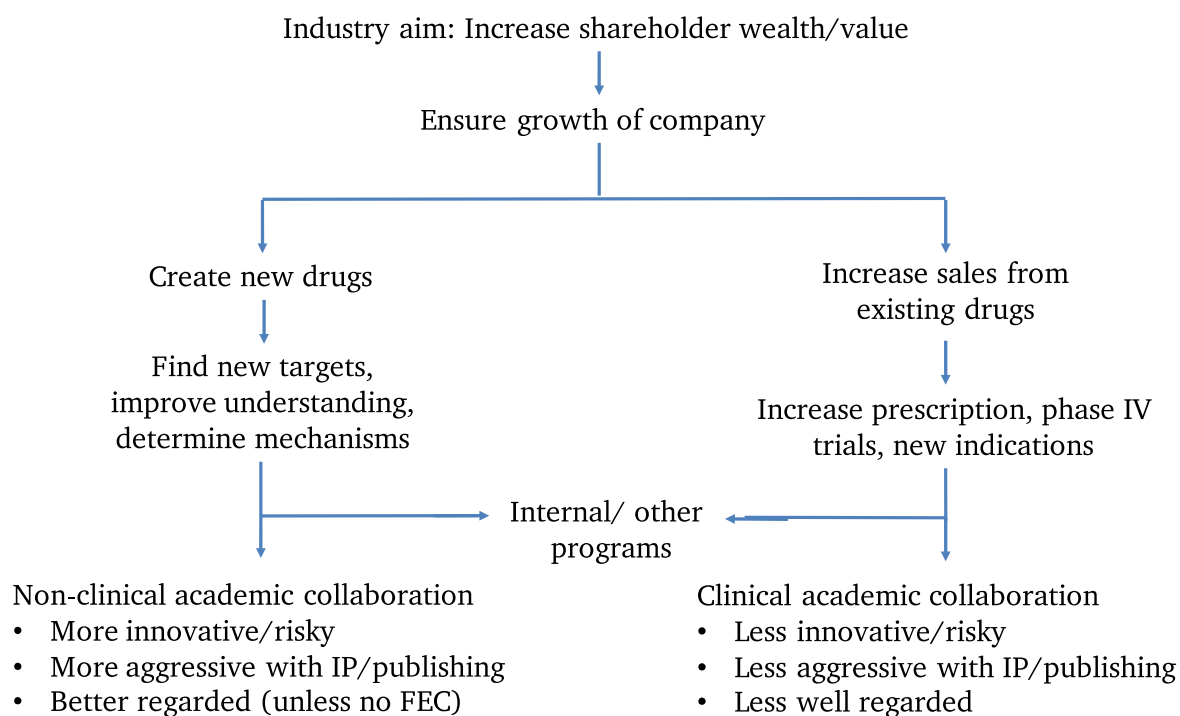


Figure 4.3 Schematic showing how different industry aims for clinical and non-clinical collaborations may contribute to different perceptions within these sub-cultures.

4.2.4.1.5 Institutional factors

Finally, some barriers seem to relate to specific institutional characteristics of the university or industry, rather than a fundamental cultural difference between academia and industry. Other than the ambiguity over the meanings of job titles in industry (more common for larger companies), in the university these barriers related to inefficiencies in the contracting process, patenting process, and guidance given to PIs.

Academics were unhappy with the way that contract negotiations occurred, felt that the propensity of OUI to let patents lapse sabotaged the commercial viability of their research. They also felt uncertain of how collaborations work or where to get that information, instead making the same mistakes as other academics who had collaborated before them. These issues are internal to the institution and may represent 'low hanging fruit' for potential strategies to substantially improve the collaboration experiences of academics.

4.2.5 Strategies to improve collaboration

The strategies that arose from the survey have been rewritten as potential strategic 'aim' – targets that any strategy to improve collaboration should aim to achieve (Table 4.7).

These strategic aims are based on changes the university could make, and cover the different aspects of initiating, supporting, and maintaining collaborations. Each strategy is discussed below.

Table 4.7 Original and Refined Strategies

Original Strategies from Chapter 3	Refined Strategic aim	Potential barrier(s) addressed
6. Establish an incentive system within the university that recognises or rewards academics for working with industry.	To encourage and attract new researchers to engage with industry	Inadequate recognition and incentives for collaboration Less well perceived by university, committees and the public (CLINICAL)
1. Create a database of all known industrial partners and their interests. 2. Form a group or department within the university to help identify, facilitate and maintain partnerships. 4. Host targeted joint events to 'showcase' academic research and enable networking. 5. Increase exchange of personnel between academia and industry	To help connect an academic researcher with the right company and individual for their needs	Navigation issues, finding the right person within a company
7. Use experienced academics to mentor junior researchers. 2. Form a group or department within the university to help identify, facilitate and maintain partnerships. 8. Reduce the cost of overheads within the university	To provide guidance on how to engage with industry, form relationships, and what to expect during collaboration	Industry change focus and 'drop' projects High turnover of personnel in industry Lengthy contract negotiations, especially due to disagreements over IP and FEC Industry restrictions on publication and data sharing (NON-CLINICAL) Industrial restrictions on time and focus limit academic freedom Lack of guidance on collaboration
3. Streamline standard contracts to expedite the formation of partnerships	To streamline the contracting process	Lengthy contract negotiations, especially due to disagreements over IP and FEC
N/A	Improve management of IP to maintain patents for longer	University allows patents to lapse too early

4.2.5.1 To encourage and attract new researchers to engage with industry

This strategic aim stems from the findings in Section 4.2.2, that industrial collaboration aids the process of translation and should be encouraged. Non-collaborating academics may be working under the assumption that published academic research is ‘picked up’ from the literature and developed into viable interventions by other groups or companies, whereas this was perceived as fallacy amongst some collaborating academics, who highlight the need for academics to drive the development of their own research. The university could work to increase collaboration among its researchers, both by promoting ways in which academics can work with industry, and by creating incentives to encourage them to do so. For example, incentive systems in academia could be changed to reward other outcomes (such as clinical trial phases) as highly as publication. One such way in which the recognition of such activities is already changing can be seen in the inclusion of ‘impact’ as an assessment factor in the 2014 Research Excellence Framework exercise for assessing universities, however the metrics by which ‘impact’ is assessed would need to be expanded to include collaboration. Such incentives may reduce suspicion and help ‘normalise’ working with industry, especially for clinical academics. Ultimately, in a climate of risk-averse funding bodies and budget cuts, academics may see industrial collaboration as a necessary component of their funding portfolio, complementary to funding from charities and research councils.

4.2.5.2 To help connect an academic researcher with the right company and individual for their needs

Identifying an appropriate contact within industry was a key barrier to those academics wishing to instigate collaboration. While four of the original strategies identified ways of doing this, these were regarding with varying levels of enthusiasm. Academics were

particularly disdainful of the idea of a database due to the high turnover of personnel in industry, stating that it would immediately be out of date and require constant updating. It was also seen to 'miss the point', overlooking the critical role that relationships and personal rapport play in collaboration. Academics stressed how personal relationships with companies formed the basis of their most successful collaborations, irrespective of the specific project outcome. Through the formation of relationships, academics felt able to understand, account for and even prevent events such as the sudden withdrawal of funds. Many academics also highlighted the need for 'genuine collaboration', rather than a mere transaction, and academics described forming relationships by participating on company advisory boards, and when post-docs or staff transferred to jobs in companies.

None of the strategies were well-regarded by all academics, and it seems that a combination of the suggested and other strategies will be required to improve navigation. However academics were most optimistic about the increased exchange of personnel between academia and industry. This was seen as an effective way to 'bridge the culture gap' and minimise the impact of changes to industry strategy on academic research programs. This supports the literature on boundary-spanning as a way to bridge cultures (see Section 1.2.2.1). Interestingly, despite five academics having previously worked in industry, the perception existed that the flow of personnel was primarily one way: out of academia and into industry, with the reverse rarely occurring. This was seen to be because of the higher barrier to entry in academia – strong competition for jobs in which applicants are assessed on their publication record and teaching experience (which candidates outside of academia are unlikely to cultivate to the same extent). This is of note, particularly because the two interviewees with the most grants from industry had prior experience working in industry themselves, implying that those who do have experience working in industry may be better at attracting collaborations. If true, this 'one way' traffic of personnel presents an interesting target to improve relationships between academia and industry.

4.2.5.3 To provide guidance on how to engage with industry and what to expect during collaboration

Academics described being unsure of what to expect from collaborations, and making common and simple mistakes when learning how to work with industry. Improving this may not only enable academics to better plan for industry interactions, but also reduce institutional barriers that occur between the academics and university administration.

The idea of a group or department helping with this was met with mixed feelings, with many academics again feeling that such a group neglects the important role of relationships in collaboration. Interestingly, one group that was not often mentioned with respect to helping provide guidance on collaboration was the Business Development (BD) office, a group within the University that aims to “support engagement with industry”, including through the identification of “areas of research alignment and to promote and facilitate both clinical and pre-clinical research collaboration”(MSD, 2016). However, BD was only known of by four out of the 26 PIs interviewed, and were described as having ‘zero profile’. Where BD were known, however, it was highly regarded. When informed of BD and the role they play, academics were optimistic but said they needed a higher profile within the department, and many confused them with OUI. As BD already exists, and has a positive track record amongst PIs who have experience of them and often plan joint events with academia and industry, understanding how this group interacts with academics may provide a fruitful way to understanding how to best provide guidance.

4.2.5.4 To streamline the contracting process

This strategy was well considered amongst interviewees, all of whom experienced the contracting process as a major hurdle. Academics felt that the main sources of contention during negotiations were predictable (generally IP and overheads), and that the university should be able to determine pre-negotiated contracts that allow for an

acceptable compromise. Collaboration with the same company should be able to use the same contracts.

4.2.5.5 Improve management of IP to maintain patents for longer

As industry were seen as unlikely to develop a product if it was not patent protected, maintaining university patents for longer could be a key way to ensure that university research is attractive to industry and therefore more likely to realise its value. This barrier was not identified during the literature review or questionnaire, and highlights the advantage of interviews as a research method able to elicit new data. In order to achieve this strategic aim more information is required about why patents are dropped. However, wider considerations could also be investigated. For example, the university could lobby for the patent system in the UK to be reviewed, taking into consideration, for example, the US patent system, where academic publication is not considered a novelty-destroying disclosure. In this way, academics can publish their research without compromising the commercial viability of an invention, perhaps contributing to the success of the US universities in producing both patents and publications.

Alternatively, it is possible to question the role of patents in drug development. That an invention may be highly effective, and yet not be developed because it is not able to be patented, seems wasteful not only of funding, but also of patient benefit. Perhaps a system needs to be established where industry are not necessary for the translation of academic inventions. This may mean developing incubation centres, changing the way that drugs are reimbursed such that the efficacy of the drug is valued, or changing the clinical trial system to a more adaptive model to enable it to be traversed by academic groups or smaller companies.

4.3 Discussion

The aim of these interviews was to answer the three research questions as outlined in the introduction (Section 4.1):

- Study question 2a) What role do academics perceive industrial collaboration as playing in the development of their research?
- Study question 2b) In what ways do barriers to collaboration affect PIs at the University of Oxford? Which barriers are perceived to have the greatest impact?
- Study question 2c) Which of the suggested strategies (from Chapter 3) are perceived by academics as being the most useful? How might they be implemented?

In response to questions 2a), industry involvement was seen as an important, if not vital, component of translation. For non-clinical research, industry facilitated translation through the provision of funds for riskier, more expensive research that academics were unable to get funding for otherwise. This supports the postulation in the previous chapter (Section 3.2.2) that industry ‘plugs gaps’ in both funding and knowledge, greatly facilitating the translational process. For clinical research, industry catalyses translation by providing access to drugs, data and regulatory expertise that enable academics to conduct relevant high quality research. While some drug development may be possible through a purely academic framework, industry provide the tools, resources and expertise that accelerates and improves the quality of the process. These data suggest therefore that industry-academic collaboration can make the process of translation more efficient, and should therefore be encouraged. That industry funding the most innovative non-clinical research, and plugging a gap left by Research Councils and charities is surprising, and suggests that academics should try to achieve a diverse funding portfolio comprising all three of these groups.

Question 2b) is responded to in Section 4.2.3 and 4.2.4 of this chapter. Barriers could be linked to differences between academic and industry cultures of data-sharing, money, and time, differences between clinical and non-clinical collaborations, and institutional processes. There was no consensus amongst academics regarding which barriers are the most important. However, the barriers that were discussed most frequently, and with the most fervour, during interviews related to the contracting process, the payment of overheads, and intellectual property. These also tended to be the barriers with the most serious consequences for the academic, including missed funding opportunities and damaged relationships with companies. These barriers related primarily to institutional processes, and conflicts between academics and university administration. As such, these are factors that the university has some influence over, and there appears to be scope for improvement in several of these. Indeed, it seems that resolving barriers during the collaboration process may be 'low hanging fruit', as changes could be implemented by harnessing the infrastructure already existent within the university, and could potentially result in substantial improvements to the collaboration experience for both academia and industry. Furthermore, barriers encountered at the collaboration process were ubiquitous amongst PIs, whereas the experience of cultural factors seemed to vary according to whether the PI was clinical or non-clinical, in addition to sometimes being dependent on features of the industry partner. Therefore, addressing such cultural barriers, which, by their nature, are more nebulous, may be difficult as they are experienced so differently by interviewees.

It may be the case that cultural barriers are generally perceived as less disruptive because barriers encountered during the collaboration process act as a limiting factor, preventing their full extent from being felt. Alternatively, it is possible that the measures taken when establishing the terms of the collaboration process then reduce the formation of cultural and environmental clashes. For example, if the contracting process was made less stringent it may be the case that academics perception of industry demands regarding

reporting and IP would intensify. Furthermore, perhaps academics who are able to traverse this difficult aspect are more likely to be able to adjust to industrial cultures. However, considering the data, focusing on resolving the barriers present in the institutional processes surrounding collaboration provides the greatest opportunity for improvement with the least investment of time and money, and will be the subsequent focus of this thesis

In response to question 2c), when evaluating potential strategies to improve collaboration arising from the survey, no single strategy was seen as helpful by all academics, with all strategies being viewed as both useful and impractical by at least one academic. This implies that no single strategy can address a barrier for all academics, and a multi-strand approach should be used. Five strategic aims were hypothesised as capable of improving collaboration for a wide range of researchers (Section 4.2.5). These strategic aims focus on changes the university can make to improve the uptake, support, and fulfilment of collaborations, and have the potential to improve both institutional processes and contribute to reductions in cultural barriers through the normalisation of collaboration. In order to investigate the effectiveness and feasibility of these strategic aims, and to understand the precise ways in which they can be achieved, further understanding is required of the flexibility and constraints surrounding these areas, information that transcends the expertise of academics. The groups best situated to explain these factors are most likely the groups involved in facilitating collaboration at the University: Research Services, Oxford University Innovation, and Business Development.

Finally, it is important to consider whether the methods used were sufficient to address these research questions. The use of both a questionnaire and interviews enabled a triangulation of results to mitigate the impact of weaknesses associated with the use of each of these methods. For example, in the questionnaire differences in comprehension

and interpretation may skew the data where phrasing is ambiguous, however this was controlled for, as much as possible, by thorough testing and piloting prior to launch. The use of a typology of barriers in the questionnaire enabled a better understanding of which barriers were more or less important to academics in translational medicine. However, it also restricts the ability of the academic to provide bespoke responses, and has the potential to overlook important nuances, as respondents may approximate their experiences to fit a barrier in the typology which does not accurately reflect their experiences. The subsequent investigation of barriers via in-depth interviews with academics enabled such nuances to be identified, and allowed for the emergence of new barriers (for example, the propensity of OUI to drop patents).

4.3.1 Summary and next steps

The data presented in this chapter provide a deeper insight into the experiences of academics within the University of Oxford who collaborate with industry in the field of biomedicine. Many factors were found to influence this experience: the size of company, the type of interaction, disease indication (rare versus common diseases, patent landscape), the location of the academic group and the clinical versus non-clinical basis of research. Despite this, there were areas of commonality in the experiences and perceived barriers to the collaboration process, particularly contracting, overheads and IP, where frustration was strongly expressed. However, the opposite view was also expressed robustly. It would be useful to understand the basis underlying both these positive and negative interactions. Furthermore, the next stage of this study seeks to evaluate the efficacy and feasibility of the five strategic aims outlined in Section 4.2.5. The knowledge to assess these strategic aims does not appear to reside within academics, and therefore for the next phase information was sought from the three groups within the university that have direct contact with both academics and industry: Research Services,

Oxford University Innovation, and Business Development. These three groups are responsible for contracting, intellectual property and the formation and maintenance of relationships with industry, respectively, and represent an attractive source of data for the final stage of this study. Insights from such groups were sought to help refine and assess the strategic goals, in addition to devising possible strategies to achieve them. In pursuit of this, the following research questions were posed for further investigation in the final research stage:

- Study question 3a): What are the constraints of facilitating groups within the University of Oxford?
- Study question 3b) How feasible is the implementation of identified strategies to improve collaboration?

Chapter 5: Interactions with facilitating groups at the University of Oxford

5.1 Introduction

The analysis conducted in Chapter 4 identified five key aims for strategic improvement:

- 1) Encourage and attract new researchers to engage with industry
- 2) Help connect an academic researcher with the right company and individual for their needs
- 3) Provide guidance on how to engage with industry and what to expect during collaboration
- 4) Streamline the contracting process
- 5) Improve management of IP to maintain patents for longer

The data from Chapter 4 suggest that achieving these aims would improve the process of industrial collaboration for academics, and furthermore could also represent 'low hanging fruit' if realised by harnessing the university's existing infrastructure. However, in order to evaluate the feasibility of implementing these strategies, information was sought from the three groups within the university that have direct contact with both academics and industry: Research Services (RS), Oxford University Innovation (OUI), and Business Development (BD) (Division, 2015). These three groups are responsible for contracting, intellectual property and the formation and maintenance of relationships with industry, respectively, and are an attractive source of data for the final stage of this study. Insights from such groups were used to help refine and assess the strategic goals, in response to the following research questions:

- Study question 3a): What are the constraints under which facilitating groups within the University of Oxford operate?
- Study question 3b): How feasible is the implementation of identified strategies to improve collaboration?

The aim of the research in this chapter, therefore, is to improve understanding of interactions between PIs, industry, and facilitating groups, and to determine whether the five key strategic approaches for improving the collaboration process for PIs could feasibly be achieved.

As more than one party is often involved in the process of establishing collaborations, the results in this chapter are presented as they relate to key constraints and arising themes, as opposed to outlining the experiences of each group. This enabled multiple perspectives around a single issue to be taken into consideration, allowing for a more nuanced analysis of barriers and strategies. Additionally, this approach is more amenable to maintaining confidentiality as specified during the ethics approval process, as only one lawyer and two members of business development were interviewed. This chapter begins by outlining the structure of the university, the function of each facilitating group, and describing the processes they oversee that are relevant to collaboration. The resulting themes from the framework analysis of interview data are then presented in terms of a) the limiting factors that impact facilitating processes, and b) the perceived causes of these limiting factors. Finally, the data are discussed in the context of the two research questions defined above.

5.1.1 University structure

The University of Oxford has a de-centralised or federal structure, by which funding is brought into an individual division, with a portion allocated back to the central university (UAS, 2016). This enables divisions to operate independently of, and in different styles from, one another according to their own needs and income. A simplified overview of the structure of the university as relevant to this thesis is provided in Figure 5.1a. Three groups participated in this study: Research Services (RS), Oxford University Innovations (OUI), and the Business Development Office (BD). Figure 5.1b illustrates the interactions of support networks within MSD and with external organisation. As shown, both BD and OUI (referred to under its previous name 'Isis Innovation' in Figure 5.1b) facilitate knowledge exchange with external groups, while RS liaises with BD and OUI in addition to several other groups, without directly facilitating the transfer of internal and external resources.

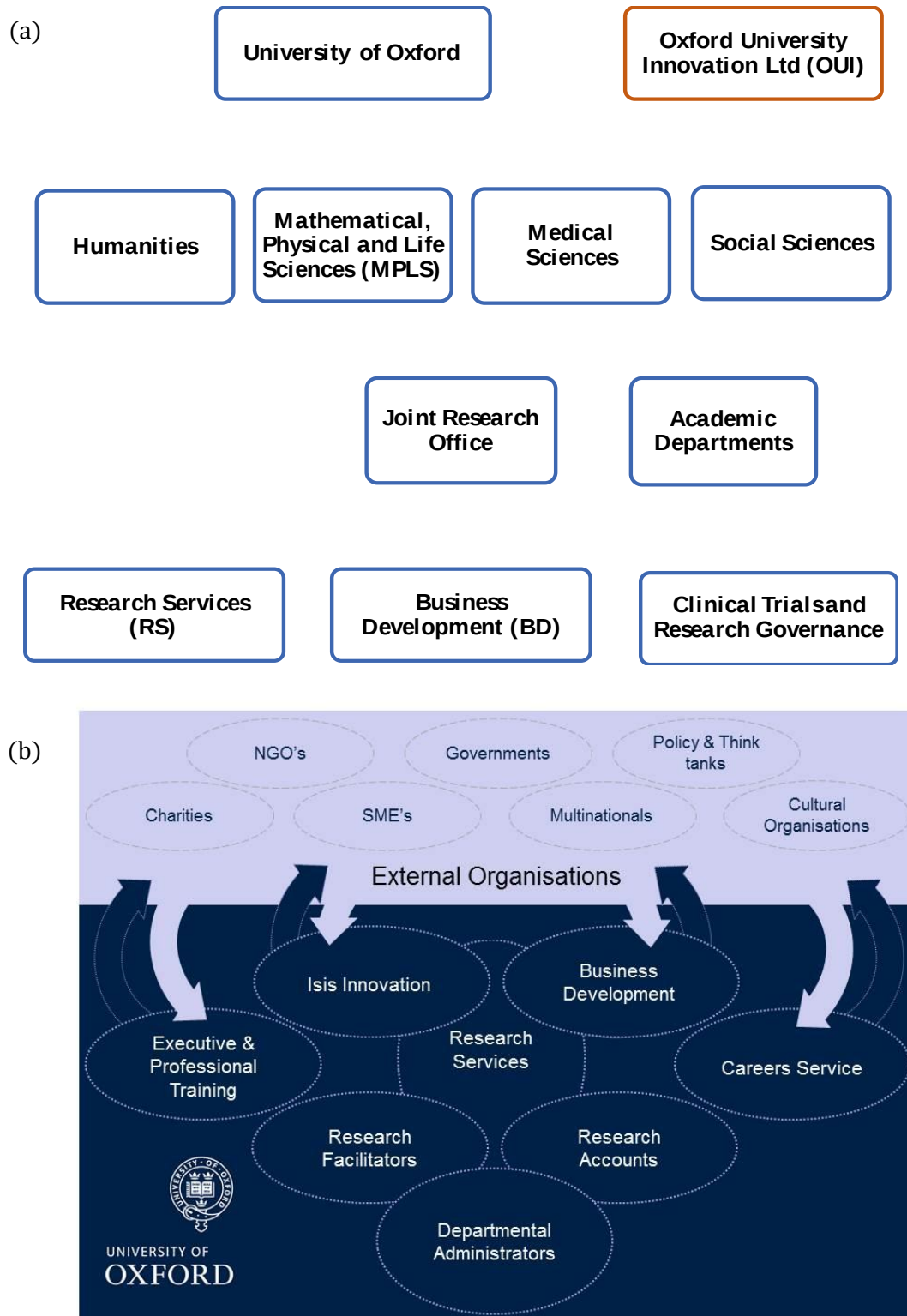


Figure 5.1 Overview of university structure and interactions with external organisations.

(a). Simplified overview of University of Oxford structure, (b) the wider research support network for medical sciences, from (OUI, 2016c)

5.1.2 Facilitating groups

This section presents an overview of the roles of each of the three facilitating groups.

5.1.2.1 Research services

The MSD Research Services (RS) is part of the University and Administrative Services at the University of Oxford. It is located in the Joint Research Office (JRO), alongside the Business Development Office and Clinical Trials and Research Governance (CTRG) (Figure 5.1). RS is responsible for addressing the administrative research needs of academics, in particular by authorising and negotiating all contracts that facilitate research. With relation to industrial collaboration, RS aids in contract negotiation, supporting grant applications, advising on costing and pricing, ensuring compliance with regulatory and sponsor requirements. Through these activities RS aims to support knowledge exchange activities and facilitate technology transfer (Services, 2016).

Contracts are required for setting out agreed performance requirements and the terms of any future eventualities. RS is designated by the University of Oxford to review all research-related contracts and to ensure that such agreements are acceptable under the university's policies, and consistent with its position as an educational institution with charitable status, as set out in set out in the university statute (Statute XVI).

For the MSD, RS comprises a group of approximately 14 staff responsible for processing and negotiating all contracts within the Division, up to approximately 3000 contracts annually (10 contracts per day). Each of these contracts must be processed through one of the three designated signatories within the university. All academics interviewed in Chapter 4 had experience working with RS.

5.1.2.2 Oxford University Innovation

Oxford University Innovation Ltd (OUI) is a technology transfer company wholly owned by the University of Oxford. In addition to technology transfer activities, it also comprises Oxford University Consulting, and Isis Enterprise. OUI manages the University's intellectual property portfolio, and aids departmental staff who wish to commercialise their work through licensing, consultancy, or the formation of spin-out companies. OUI also aids in the application for translational funding awards from charities and Research Councils, in addition to providing translational funding itself to support proof-of-concept studies within the university. In total, OUI had revenues £24.6m in 2015, distributing £13.6m back to the University (OUI, 2016a). While OUI deal with many types of IP, based on discussions with academics, the focus of the results outlined in this chapter pertain mostly to the commercialisation of patents, either through licensing the patent to a new company, or by creating a new (spin-out) company to which the patent is licensed. OUI were ranked 10th best technology transfer office (TTO) in the world in 2014, and was the highest ranked outside of the US (Bayes-Brown, 2014).

5.1.2.3 Business Development

Business Development (BD) is an in-house team for the Medical Sciences Division (MSD) focussed on providing support for academics engaging in research and innovation with industry. In this role, they aim to “identify areas of research alignment” and to “promote and facilitate both clinical and pre-clinical research collaborations”, aiding both companies and academics seeking partners (MSD, 2016).

5.2 Results

5.2.1 Data collection and analysis

In total, 23 semi-structured interviews were conducted with 17 individuals, using a separate topic guide for each group, informed by previous research stages outlined in Chapters 3 and 4, and in the case of OUI, existing literature on TTOs (Appendices vii, viii and ix). Interviews took place at the groups' respective offices, and in some cases access was restricted by time constraints and gatekeepers (Seidman, 2013). In cases of multiple interviews with the same participant (as conducted in RS and OUI), this was generally due to one of three circumstances: a) the original interview session was interrupted, b) the interview had reached the allotted time and the interviewee wished to continue the interview at a later date, or c) where follow-up interviews were conducted to review finding and develop new lines of understanding.

Within RS, formal, semi-structured interviews were conducted with four team members, with two members being interviewed twice, making six recorded interviews in total. Further discussions with four other team members (which were not recorded) and the attendance of team meetings allowed for clarification and the refinement of themes. During the course of the interviews a schematic was developed in order to better understand the contracting process and to highlight the main 'bottlenecks' preventing progress (see Figure 5.2). This schematic was subsequently refined through iterative communications with RS, and used to inform further interviews with team members. Upon the advice of RS, an informal interview with an external lawyer who has worked with the university was also conducted. Within OUI, seven interviews took place with six representatives of varying seniority over a two-week period. In a similar way to RS, a schematic of the patenting process was developed in early interviews and used in subsequent discussions. Within Business Development, four interviews were conducted with two representatives. One participant was interviewed and recorded once, and

further clarification was sought on two further occasions to develop analyses. Another participant was interviewed but this was not recorded at the specification of the interviewee. Interviews varied in length from 30 to 90 minutes, and were recorded (where possible), transcribed, and analysed using the framework method in the manner as outlined in Section 2.3.3.3. A full list of interviewees can be found in Appendix x.

5.2.2 Process Overviews

In order to understand the constraints of facilitating groups, and answer the first research question outlined in Section 5.1, an understanding of the key process that each group oversees was pursued. To aid this, a general schematic of the process was constructed with input from the groups and used as an aid in further discussions of groups' constraints and process bottlenecks.. For RS, a schematic of the contracting process was developed (Figure 5.2, Section 5.2.2.1), and for OUI a schematic of the patenting and licensing process was deduced (Figure 5.3 Section 5.2.2.2). The derivation of a standard process for Business Development was not perceived as relevant by group members due to the heterogeneity of activities within the group. BD aims to form relationships with companies, a task which is more variable in nature than IP or contracting, but as outlined in Chapter 4, perceived by academics as extremely important in collaboration. An outline of the role and activities of BD is provided in Section 5.2.2.3, with a description of their limiting steps.

Table 5.1 lists the limiting steps for each group alongside the academic perception of that group, summarised from data presented in Chapter 4.

Table 5.1 Relating academic perceptions of facilitating groups with their constraints.

	Academic Perception	Limiting Steps
RS	- Contracting process as slow, obstructive, pedantic - RS pursue items of low importance to academics (e.g. overheads, IP) to an unreasonable extent - Can result in lost funding and collaborations, and the university being perceived by companies as 'difficult'	- Hard to obtain all necessary information from academics - Academics contact RS too late in the process, once promises have been made 'Waiting game' for responses from company and other groups within the university - Negotiating 'sticking points' on publishing, overheads and IP.
OUI	- Too 'greedy' in their IP negotiations - Poor at finding licensing partners as do not understand the science - Allow patents to lapse too soon	- Navigation – hard to identify the right person in industry - Limited awareness of industry research interests due to industry secrecy - Academic interference in negotiations
BD	- Where known: helpful, useful - Otherwise, unknown, and academics perceive the university as providing no guidance on collaboration and navigation within companies as a key issue	Limited awareness of research interests of PIs

BD – Business Development, OUI – Oxford University Innovation, RS – Research Services

5.2.2.1 The Contracting Process

In the form of a flow chart (Figure 5.2), the contracting process is deconstructed into each of the individual steps required for the assembly of new contracts, along with key questions that need to be answered at that stage. The flow chart works for many types of contracts⁴ and primarily applies to two-party (as opposed to multiparty) agreements.

Members of RS highlighted that most contract negotiations proceed unencumbered, representing only a few minutes' work for each party. However, this is not always the case, and the main grievance levied against RS by academics was the length of time that contracting takes, with several academics describing the process taking upwards of a year. This delay was seen as impeding research progress and resulting in industrial collaborations stalling or failing due to changes in industrial focus. When investigating the difference between contracts that take 'a few minutes' and contracts that take 'over a year', it was discovered that when substantial delays do occur, they tend to be as a result of two bottlenecks in the process: 'review and data gathering' and 'marking-up'.

5.2.2.1.1 Limiting steps – Review and Data Gathering

During Review and Data Gathering RS need to collect sufficient information to draft an agreement. This includes information on both the project itself (including an explicit description of the work that will be done by both parties, any contributing background IP, a project plan with aims and objectives, an overview of the expected outcomes of the research and what the academic wishes to do with those outputs, and a full costing by the departmental administrator) and on any other agreements the academic is party to, for example previous funding or IP agreements, as these may restrict the scope of the new

⁴Contracts referenced here include: CDAs – confidential disclosure agreements, MTAs – material transfer agreements, service agreements, and collaboration agreements.

contract. Obtaining this information from academics and other university groups can take weeks or months. The process of drawing up a single contract may require input from several different departments within the university, including OUI, BD, CTRG (clinical trials research and governance), Legal Services and Ethics. Waiting on replies and confirmation from these groups prevents RS from being able to draw up an agreement, and is a key source of delays within the contracting process. However, there are interactions with one group RS experiences to be a particular cause of delays - the industry partner. Here, RS have no control over how long it takes to get a response, and are unable to manage the expectations of the academics because the rate of response from a company is so unpredictable. Furthermore, the idiosyncrasies of working with companies as opposed to other universities are evident. For example, smaller collaborations may be of low importance to a company, which has other focuses that prioritise the time of its legal team, sometimes leading to industry returning contracts that have 'barely' been looked at and are not fit for purpose. Slow responses from industry impact both data gathering and 'marking-up'

5.2.2.1.2 Limiting steps – 'Marking-up' and Negotiation 'sticking-points'

The second bottleneck is during negotiations - the process of 'marking-up' an agreement. For RS, negotiations on the terms of contract begin once all the necessary information is received from both academics and industry and the terms of the project have been established. All agreements start from a template contract, either from the University or the company, but if the industrial template is used, the university edits or 'marks-up' this template to make it fit with university policy. After this point, several iterations may be exchanged where both parties make small concessions as they progress towards a mutually agreeable contract. RS described particular difficulties in negotiating with industry over key 'sticking points'. Negotiation 'sticking points' are common sources of disagreement during negotiations. These sticking points are a result of areas where the

university is unable to compromise due to the mandate specified by the university's charitable status: to deliver "public benefit", with any arising private benefit being "justifiably incidental" (TCC, 2014). This means that the university cannot conduct research for the primary benefit of a private institution, even if that does bring in funds to support other research activities within the university. The balance must favour public benefit, a large part of which involves publishing and the dissemination of data and information. There are three key 'sticking points', described as 'holy ground' that the university has to hold a strict position on. These are publishing, overheads (FEC), intellectual property.

Publishing is one of the most hotly contested areas with industry, as is not only an important factor for the academic, but also an important output in delivering public benefit. Due to pressures to protect IP, industry often want the final go/no go decision on publication, something that the university can under no circumstances agree to, as it goes against the university ethos and may preclude the possibility of public benefit arising from the collaboration. Additionally, if the ability to publish is restricted it may reduce the ability of the academic to use those data in future research, which can be especially problematic if the work is conducted as part of a doctorate or post-doctoral project, where the future employability of that individual may depend on publications. However, the university is able to compromise to a certain extent, for example, by extending a one month publication review period to three or six, allowing the company to protect any arising IP. Interestingly, academics did not perceive publication as a negotiation issue, but described experiences of industry restricting their ability to publish regardless. This indicates that academics are not aware that RS negotiate for their ability to publish freely, and may indicate that industry are trying to influence publishing irrespective of the terms of contract.

Another negotiating sticking-point is that of paying overheads, or the full economic costs (FEC) of a project. The university policy states that industry should pay a minimum of 100% FEC in order to reduce the cost deficit incurred when receiving other types of research funding that do not attract full overheads. The FEC of research includes three costs: 1) the directly incurred costs of the project, 2) directly allocated costs such as the costs of the PI's time, and 3) indirect costs, such as those for maintenance, estates and the use of existing university equipment. The addition of the second and third of these substantially adds to the overall cost of the project, sometimes doubling it, an additional charge industry is reluctant to pay, and often push back against. Academics themselves do not always see the benefit of these extra charges, which are absorbed by the department and central university. Therefore, where collaborations do not occur due to disagreements over FEC, academics can see the university is being unreasonable, and unwilling to accept less than a 100% overheads with the result of that academic receiving no funding at all. In reality, the university is bound by the HEFCE Financial Memorandum, which states that: "Institutions are expected to recover, in aggregate, the full economic costs of all their activities... we do not expect public funds to subsidise non-public activities", (HEFCE, 2014a). Therefore, if a PI agrees a project price for less than 100% FEC then RS need to know where the remaining funds are coming from. Generally, any outstanding costs are covered by research income from other funding bodies, each of which comes with specific terms and restrictions regarding what their funding can be used for.

This relates to the final negotiating sticking-point – IP. If a company is not covering all costs then the university is restricted in its ability to delegate arising IP, as terms of contract from other funding bodies must then be reviewed. Research Services are able to be more flexible in agreements where industry pay 100% FEC because no existing agreements restrict the terms of the new contract. Thus, there is a close relationship between the percentage of overheads paid and the freedom of the university to designate

IP. However, even in cases where a company is paying 100% FEC, the university must still ensure that it is primarily producing public rather than private benefit.

Negotiations over IP have a difficult dynamic because IP is particularly important to industry in translational medicine, and often a low priority to academics. Some academics highlight how they are happy to assign all rights to the company to ensure a quick negotiation. However, by doing so, they may be precluding themselves from being able to work with that molecule or even in that area once the project has finished, as all rights will belong to the company. RS highlighted how academics were often unaware of how contracts protect their freedom to conduct their research.

Finally, members of RS described how industry partners negotiate 'harder' than other groups such as charities or other universities. Industry contracts are seen as 'scary' because industry have a markedly different goal from the university – to make money. This can further delay the contracting process in two ways. Firstly, contracts may require more iterations as industry fight harder for the terms they want. Secondly, this can cause RS to behave with more caution as they are concerned about making a mistake and 'giving away' an important term to industry.

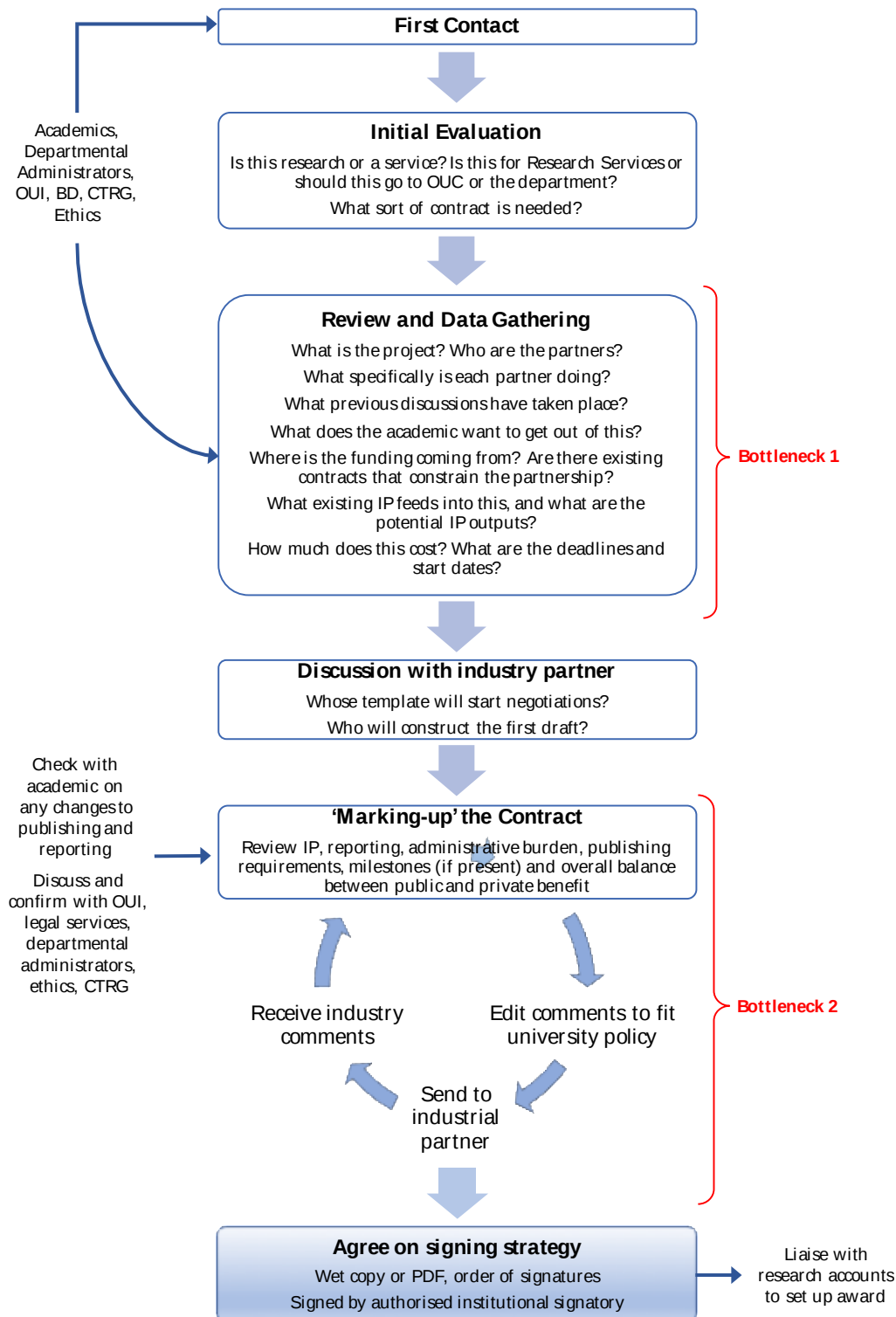


Figure 5.2 Overview of the contracting process for two-party agreements. RS – Research Services, OUC – Oxford University Consulting, OUI – Oxford University Innovation, CTRG – Clinical Trials and Research Governance, BD – Business Development, IP – Intellectual Property.

5.2.2.2 Patenting and Licensing

All patents in the UK must undergo the same process once a patent application has been filed (EPO, 2016). In the case of OUI, the process from disclosure (where a potential invention is first brought to OUI) to licensing involves a number of decision steps, as outlined in Figure 5.3a. First, a disclosure is evaluated for its patentability and market appeal, and a likely commercialisation route identified, before an initial patent application is filed. From this point, the ‘clock starts ticking’, and regular milestones mark the progression of the patent, each of which incurs a cost. The longer the patent is active, the more the costs accumulate, as shown in Figure 5.3b. If at any point OUI decide not to pursue the patent, they offer to assign the rights to the funders of the research, followed by any inventors or contributors, who would then be responsible for the costs of the patent. If none of these groups want the patent, then the patent lapses, releasing the information contained within into the public domain where it can be freely used. While participants did not describe process ‘bottlenecks’ in the same manner as members of RS, there were two key limiting factors that were seen to impede the licensing process and contribute towards patent lapses – finding industry partners and negotiations.

5.2.2.2.1 Limiting steps – finding partners

For OUI a key limiting step is gaining information on industrial research interests. As shown in Figure 5.3b, the costs of maintaining a patent increase over time, therefore, OUI as a profit-motivated, budget-restricted entity, is under pressure to license the patent as quickly as possible, which involves identifying potential industry partners. When searching for licensees, OUI identifies potential partners in several different ways. The most productive of these is generally when the academic themselves suggests a partner, either a group they have had experience working with, or a person that they have met at

a conference, for example. If an academic doesn't have any existing links with companies that could be exploited, they are still a valuable source of information due to their existing knowledge of their area of research, and of the major companies within that area. When academics are not able to provide leads, OUI seek potential licensees based on the areas of research a company is interested in. However, obtaining information on the research interests of a company is challenging for two reasons: 1) industry are highly secretive of their research programmes, 2) even where recent interests are known, these are subject to change due to industry's reactivity to changes in the market. OUI discussed how forming a link or relationship with the company is helpful in keeping abreast of research issues, however where this isn't possible less productive methods of identifying potential licensees are used, including market reports, patent searches and 'googling'. Moreover, even where information on a company's research interests are obtained, OUI face a similar 'navigation' issue to academics – finding the right person in a company to start talking to.

OUI are limited in their ability to find licensing partners and maintain patents by their available resources. A limited team with a diverse and expansive portfolio is unable to 'unturn every stone' in search of a licensee. A limited budget is unable to maintain all patents until a point at which a license is found. Where a licensee is not identified, OUI can either choose to maintain the patent at cost to the group (which has a limited budget with which to file and maintain IP for the university), or can offer to assign the rights to the funders, inventors and contributors. If none of the groups chose to adopt the patent, it lapses. Allowing a patent to lapse compromises the commercial potential of an innovation, as it is no longer protected, and therefore less likely to confer competitive advantage and be of interest to industry.

5.2.2.2.1 Limiting steps – academic interference in negotiations

For OUI, negotiations occur once a partner has been identified to determine the structure of the licensing agreement. Members of OUI described difficulties negotiating with industry due to the tendency for academics to interfere, disrupting the process and causing delays. This issue was also experienced by RS as aggravating negotiations during the contracting process.

Academic interference is a conversation or negotiation that occurs between the academic and company outside of the official negotiations, and happens both prior to or during negotiations. External channels of communication between the academic and industry can result in mismanaged company expectations by an academic who may have undersold their project.

Discussion prior to contracting can disrupt negotiations by putting RS or OUI in a weaker negotiating position, especially where academics promise or agree to terms that the university is unable to comply with. Members of OUI described experiences of where, instead of starting from their preferred, strong, negotiating position, they first need to ‘unpick the mess’ of prior verbal agreements between the company and the academic.

In addition, many members of both OUI and RS had experiences of academic involvement being disruptive and unhelpful during the negotiation process itself, such as agreeing to compromises that are currently being negotiated. Both groups also described experiences of industry playing ‘dirty tricks’ by communicating their dissatisfaction with contract terms to the academic, persuading the PI that RS or OUI are being unreasonable to ‘get them to gang up’ against the group.

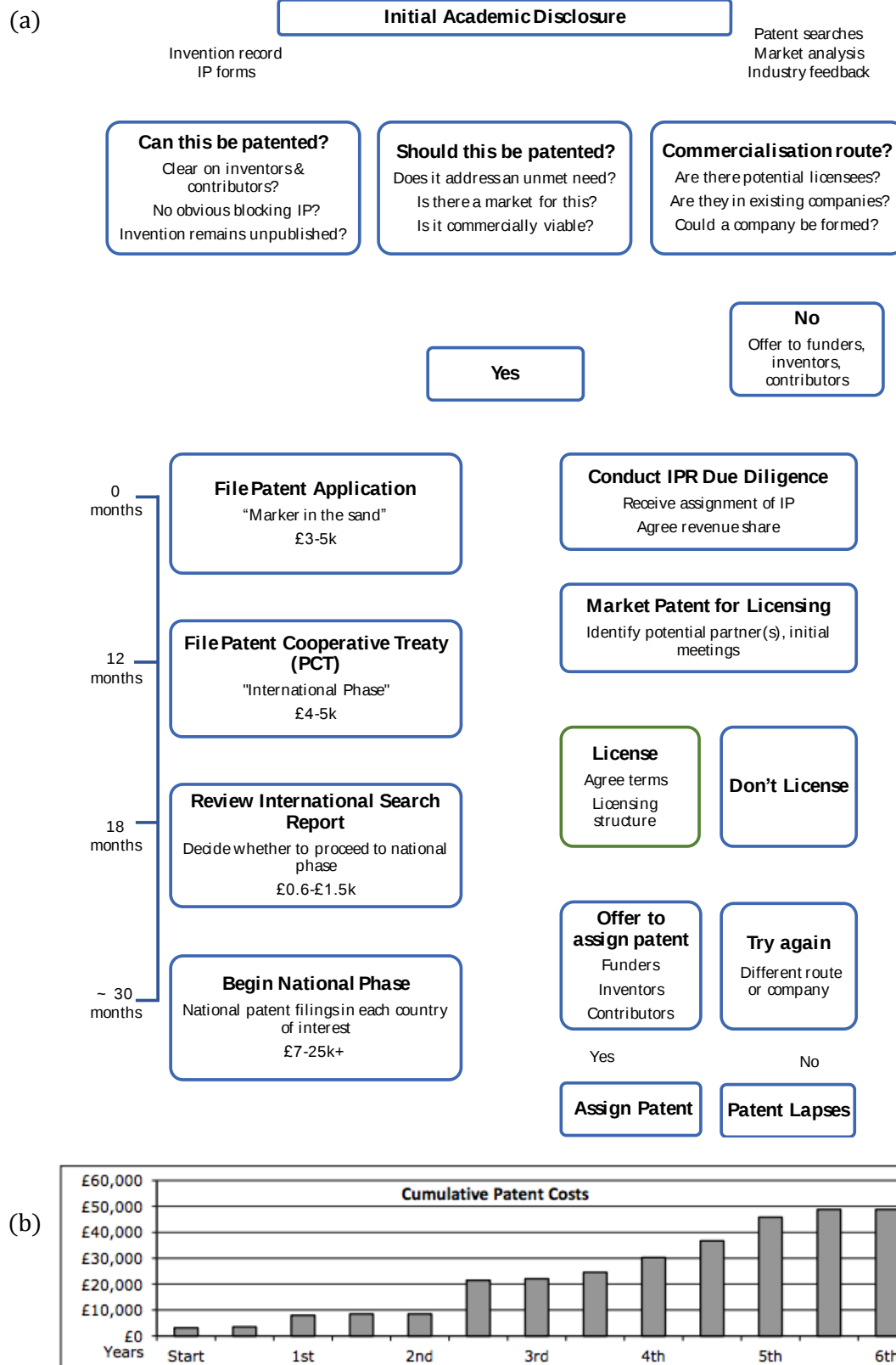


Figure 5.3 Overview of Patenting Process and cumulative costs. The stages in the patenting process along with the appropriate required time-frame (a), and the cumulative costs (b) are shown. 'Initial academic disclosure' indicates the point at which academics first engage with OUI (from (OUI, 2016b)).

5.2.2.3 Business Development: Forming relationships

Business Development (BD) is an in-house team for the MSD focussed on providing support for both academics and companies engaging in collaboration. BD acts as the primary contact point between MSD and industry, and aims to “identify areas of research alignment” and to “promote and facilitate both clinical and pre-clinical research collaborations” for both companies and academics (MSD, 2016). BD described their role as a reliable and consistent contact point as crucial in establishing trust with companies. BD use a variety of mechanisms to encourage academia-industry collaboration, including hosting joint events, organising meetings and attending conferences to advertise departmental research. Additionally, BD helps industry navigate the university system, and nurtures relationships with existing partner companies with the aim of developing smaller collaborations into larger ones entailing more projects and more funding.

BD interacts with industry both proactively, by seeking them out at conferences or sending out research summaries, or, as is more common, reactively, when a company approaches BD seeking to work with the university. BD estimates that 99% of their approaches are industry looking for an unknown partner (where the partner is known the company tends to contact the academic directly). BD are rarely approached by academics, unless they are looking for assistance in their existing partnership.

Therefore, one of BDs most important activities is finding a suitable academic partner within the university. With hundreds of PIs who have changing research interests and attitudes towards collaboration, keeping abreast of the research landscape within the university is difficult, and one of the main limiting factors for BD. When an academic partner is identified, BD also play a role in bridging the ‘culture gap’ and helping to manage the expectations of both the academic and the company.

5.2.2.3.1 Limiting steps – Finding academic partners

The information on the research landscape within MSD is BD's 'trade information' enabling them to advertise the department to potential collaborators and match academics to industry partners. However, it is difficult to get an accurate and up-to-date impression of what all of the researchers in a department are working on, as such data do not exist within the university. A resource detailing such information would be expected to be 'out of date' almost immediately, and regardless unable to reflect the dynamic nature of academia, and the 'new ideas' that emerge on a regular basis. Thus, in order to determine an academic's current research focuses, BD use data from academic researchers' websites with information gathered from meetings with PIs or by attending talks that the PIs give, although this is time-consuming and potentially inefficient. Beyond this, BD occasionally run internal funding calls in partnership with industry, where academics submit potential project applications with the goal of receiving industry funding. These project submissions are subsequently used by BD to gain insight into the current research landscape within the university. Additionally, on one occasion BD put together a mailing list of all academics working in a specific area who were subsequently surveyed on their current research focuses.

Members of BD noted how they tend to draw from an existing pool of academics contacts who they have 'vision of', potentially overlooking other academics whose research may be more appropriate or likely to result in collaboration. In this sense, the identification of partners within the university is 'hit and miss', rather than systematic. There is scope here to better harness the wide range of expertise present within the university.

5.2.3 Contributing factors

When reviewing the limiting steps above, many of the factors aggravating the core processes could be linked to one of three contributing factors: a) poor knowledge transfer within the university, b) difficulties associated with working with industry, and c) available resources within the facilitating group. A list of the limiting steps and the factors that underlie and contribute to their perpetuation is shown in Table 5.2.

5.2.3.1 Poor knowledge transfer within the university

The poor transfer of knowledge between university departments was of particular issue for BD and RS. This manifested in two main ways: 1) academics were not aware of the facilitating groups or how best to engage with them, 2) facilitating groups had poor visibility of the research activities of academics.

For RS the main contributing factor is a lack of awareness from academics on how to engage with them. Analysis of interviews with both academics and RS indicate a general lack of awareness on the part of the academic regarding several aspects. Members of RS described experiences of academics not realising that interactions they were having with other groups, for example another academic lab, could have been protected against being ‘scooped’ by using a contract. Some members of RS worked with academics who signed contracts themselves (instead of the official university signatory), leaving them personally liable for knowing and executing the terms of the contract (which, as they are not negotiated, may have very harsh terms regarding factors such as publishing). Academics were often described as contacting RS much too late in the process of agreeing a project, sometimes making promises that RS must then renege on.

Table 5.2 Limiting steps and overview of contributing factors

	Limiting Steps	Contributing Factors
RS	• Hard to obtain all necessary information from academics • Being contacted by academics too late in the process • 'Waiting game' for responses from company and other groups within the university • Negotiating 'sticking points' on publishing, overheads and IP.	• Slow response times from other groups/industry • Lack of awareness from academics on how to engage with RS • Industry unwilling to use Lambert Agreements • Outside discussions between PI and company before/during negotiations
OUI	• Negotiating 'sticking points' • Navigation – hard to identify the right person in industry • Limited awareness of industry research interests • Limited resources with which to 'unturn every stone' when contacting potential partner	• Industry secrecy and turnover • Limited patent budget and high demand • Academics encouraged to patent early, therefore less robust and less appealing to industrial licensees • Outside discussions between PI and company
BD	• Hard to find appropriate academic partners • Limited vision of PIs in department • Difficult to maintain list of industry contacts	• Lack of academic awareness of existence of group • Limited personnel to form relationships within department and understand academic research interests • Limited personnel to promote group and maintain databases/ relationships with industry

BD – Business Development, OUI – Oxford University Innovation, RS – Research Services

Members of RS described having to 'bug' academics on numerous occasions to obtain the necessary information to simply draft up an initial agreement. Academics did not seem to be aware of the information that RS need to draw up a contract, what happens to the contract once this information has been obtained, or the causes of subsequent delays. This lead to a frustration with RS, especially when delays were due to disagreements over IP and overheads, issues in which RS was seen to be 'out of touch' with academic interests.

Members of RS described academics as not recognising how the contracting process benefits them. This was especially true for aspects such as overheads and IP, which despite ensuring the continued functioning of the university and the ability of the academic to pursue that research area after the collaboration, respectively, were seen as disruptive and pedantic issues to pursue. This contrasts with the third point of contention, publishing, which is of high importance to academics. Thus, educating academics as to why these issues are important to both the university, and to them personally, may improve their experience of the contracting process.

Furthermore, this lack of awareness of how to engage with RS may lead to worse overall experiences of the contracting process. For example, academics that engage RS later in discussions with industry, feeling the full force of negotiating 'sticking-points' as RS need to start negotiating from a much later time point and potentially backtrack on any verbal promises between the academic and the company. This may delay the start of a project or allow the academic less time to do the work.

Indeed, the academics that RS have worked with a lot were seen to be the most satisfied with the process, because they understood both how to engage with RS and the cause of delays. This suggests that such awareness is acquired through experience, rather than through any guidance or information provided to the academic in advance of the contracting process. This is supported by data outlined in Chapter 4, where academics described a 'learning curve' that they need to go through when collaborating. Indeed, from

the variability of perceptions of the contracting process, it appears that even if academics have worked with RS several times before, they still may not be fully aware of what RS need or when they need it.

This lack of academic awareness was a key source of frustration for RS, resulting in unnecessary delays, disrupted negotiations and potential breach of contracts. Members of RS acknowledged that ‘the more academics understand what we need the easier this process is’. However, as discussed in Section 5.2.3.3, RS sometimes avoid academic engagement in the contracting process to reduce interference during negotiations. It is possible that this creates a self-perpetuating cycle, where ill-informed academics disrupt negotiation processes, reducing the desire of RS to involve academics during contacting, which subsequently reduces the likelihood of academics becoming better informed. This creates a break-down in effective communication that could result in negative perceptions of RS among academics.

Arguably, the lack of awareness discussed here is due to the absence of information from RS regarding their role and how they can best help academics. Considering many of the complaints about RS in Chapter 4, in conjunction with a lack of understanding about the contracting process (i.e., the aforementioned ‘black box’), it is likely that improving awareness and understanding may not only improve the academics’ experience of collaboration, but also improve the overall efficiency of the contracting process, enabling the timely provision of appropriate information and better management of relationships with the industry partner.

Academic awareness of the existence of the Business Development office was low amongst the interviewee of collaborating academics, though where it was known it was very regarded as highly effective. Some of the key barriers identified by academics (e.g. navigation within industry, guidance on culture differences, simple mistakes and what to expect from collaborations) are directly within the remit of BD, however it seems that

academics do not approach BD to ask for help because they are not aware of their role or even existence. In a similar way to RS, educating academics about how to use the tools around them could substantially improve their collaboration experience.

The second knowledge transfer for BD was an awareness of the research landscape within the department. Of those PIs interviewed for this study, only 4 out of 26 PIs having heard of the group. While BD acknowledge that they have limited visibility of academics within the department, it is surprising that academics such as these that are known to be collaborating are did not seem within that field of vision. This limited reach throughout the department limits BD's ability to best match industry approaches to academic partners. However, the scope to improve this information is limited by the available data and the ways in which BD gather information on academics – by attending talks by academics, issuing funding calls or just 'googling'. These resource intensive activities require substantial person-power, a limited resource within the group.

In contrast to RS and BD, academics were aware of the existence and purpose of OUI, as well as when to approach them. Indeed, OUI have worked to substantially increased their profile within departments over the past few years, increasing the number of disclosures (that is, academics approaching OUI with potential IP) by 23% in a single year (OUI, 2015). While it may be the case that these disclosures do not lead to patents, it is a good metric of awareness, as it reflects the frequency with which PIs actively approach OUI. Such an increase in a single year suggests increased awareness from academics regarding the role and relevance of OUI, especially as these disclosures are coming from academics who had not previously engaged with OUI. This increased awareness was seen to be the result of several pro-active internal marketing strategies implemented by OUI over the past few years: a) 'hot desking' and having staff work within their focus departments, b) providing hours of availability within OUI offices to encourage spontaneous approach, c) offering three month internships for doctoral students, and d) running workshops or

lecture series as optional courses for doctoral students. The process by which OUI have raised their profile within the university has been successful by most metrics, including number of disclosures, number of patent holdings and applications (which increased by 24% between 2013-15), and revenue (which increased by over 140% between 2013-15)(OUI, 2013, OUI, 2015, Bayes-Brown, 2014), and may present mechanisms that could be employed by RS and BD in improving their respective profiles within the university.

5.2.3.2 Difficulties in working with industry

Members of facilitating groups described difficulties encountered during their activities that were specific to working with industry. These tended to relate to one of two factors: 1) Aggressive negotiation strategies, 2) Industry secrecy over research interests.

For RS, industry's aggressive approach to negotiation delayed the contracting process and heightened members concerns about making mistakes and conceding key terms. This is in contrast to negotiations with universities, which were described as a much simpler process. Indeed, for academic partners many universities have agreed to sign up to a series of pre-negotiated contracts called the 'Brunswick Agreements'. These are a set of contracts (CDA, NDA, MTA, etc) which were drawn up by a group of universities to be implemented with minimal minimal modification beyond a description of the project. Adoption of the Brunswick Agreements is high, and the use of these contracts were seen to have substantially reduced contracting burdens for these interactions.

The use of such pre-negotiated contracts was seen to be useful in the context of academia-industry interaction because of the predictability of negotiating 'sticking points'. The university has areas that it is unable to compromise on, and must produce public benefit. Similarly, industrial partners have key priorities in negotiations, generally relating to minimising costs and maximising IP ownership and confidentiality (V. Acha, pers. comm.

13th April 2016). The predictability of areas of conflict during negotiations is a recognised phenomenon that was the focus of the 2003 Lambert Review into Business-University Collaboration (Lambert, 2003), which aimed to create a set of pre-negotiated contracts with fair and acceptable terms for all parties. This led to the 'Lambert Toolkit' in 2010 (IPO, 2010), a set of five 'Lambert Agreements' that assign IP ownership on the basis of input, from entirely owned by the university to entirely owned by the company (Table 5.3 provides an overview of the IP designation for each contract). These agreements were pre-negotiated in conjunction with GlaxoSmithKline UK and several UK universities. They were designed to be used 'as-is', requiring minimal modification and eliminating the need for protracted discussions and legal intervention. However, as revealed by the 2013 review into the use of Lambert toolkit (IPO, 2013), uptake of the Lambert agreements has been relatively sparse, with less than 10% of collaborative research in the UK based on the contracts. Members of RS stated that the low uptake of the Lambert agreements at the university was because companies were unwilling to 'take the hit' by simply agreeing to the Agreements, and would rather push for more ownership by starting from their ideal positions and negotiating to a perceived better compromise.

Table 5.3 Overview of Lambert Agreements

Collaboration agreement	Description of terms	IP ownership
Agreement 1	The university owns the Intellectual Property (IP) in the results and grants a non-exclusive licence for the sponsor and its group companies to use the results in a specified business area (field) and/or a geographical area(territory).	University
Agreement 2	The university owns the IP in the results and licenses the sponsor and its group companies to use the results in a specified field and/or territory, and the sponsor has an option to acquire an exclusive licence in relation to certain results. Sponsor may negotiate further licence to some or all University IP	University
Agreement 3	The university owns the IP in the results and licenses the sponsor and its group companies to use the results in a specified field and/or territory and the sponsor has an option to take an assignment of the IP in certain results.	University
Agreement 4	The sponsor owns the IP in the results, but rights are reserved to allow the university to use the results for academic purposes (including academic publication) on certain conditions to protect the confidentiality of the Sponsor's information and so as not to jeopardise the possibility of the sponsor obtaining a patent for the results.	Sponsor
Agreement 5	The sponsor owns the IP in the results, and the university has no right to publish the results. (This sort of agreement is usually referred to as a contract research or research services agreement, rather than a collaborative research agreement.)	Sponsor

Agreement 1 pertains to collaborations with mainly academic input, and allocates most IP to the university, Agreement 5 pertains to collaborations with mainly industry input, with Agreements 2-4 varying according to input. 'Sponsor' refers to the industrial partner.

Table and text adapted from the Lambert Toolkit (IPO, 2010)

Both RS and OUI also have experience of industry taking to Academics outside of the negotiations to try to improve their position. Again, education may be able to substantially improve this, by providing guidance to academics on how they can help RS and OUI, making academics aware of the benefits that they gain from these groups' negotiations with industry, and providing reasons why the university is unable to compromise on factors such as overheads and IP.

Another difficult aspect of working with industry was the secrecy with which they shrouded their research interests. This made it difficult for OUI to identify suitable licensing partners for university inventions. It also made it difficult to know who the right person to contact in a company was, an issue that was aggravated by the high rates of turnover of personnel in industry.

Furthermore, when considering the stage of development of the research, a key difference between academia and industry emerges. The principle of confidentiality within industry means that inventions can be worked on and developed for several years before they file for a patent. Leaving aside the possibility of the development could potentially be 'scooped' by a competitor, this extended development period conveys two main advantages. Firstly, the application is more developed, meaning there is a clearer understanding of its value and the company is able to submit a more robust patent filing. Secondly, this enables the company to delay the point at which 'the clock starts ticking', signalling increasing costs and decreasing remaining patent life.

Conversely, in academia, the primary focus is to publish. Because in most circumstances publication constitutes a novelty destroying disclosure, OUI are under pressure to file for patents before publication. The consequence of this is that the patents filed in academia tend to be for much earlier-stage, less developed technologies. This adds further uncertainty about the prospective commercial value of academic patents, and the impact of this is felt when seeking industrial partners. Industry is less willing to purchase licenses

for IP that is speculative or not considered adequately robust, especially if the full patent has not yet been granted. Members of OUI estimate that academic IP is filed for about 3-5 years before it is sufficiently developed to be of real interest to industry. a study analysing the date from initial publication of a new compound to market approval found that new molecular entities (NMEs) first published by industry are on average 12 years closer to market approval than NMEs first published by academics (Patridge et al., 2015).

5.2.3.3 Limited resources within facilitating groups

As discussed in Section 5.2.3.1, OUI have successfully increased their profile within the university over the past few years. However, the rate of success also substantially increased demand for their services, results in vast increases in the number of disclosures, the number of new patents filed annually, and an increasing existing patent portfolio that already supports thousands of filings. Consequently, OUI's patent budget was described as 'stretched to breaking point', and new inventions are evaluated with a 'quality filter' to allow OUI to invest in those projects that have the most commercial and clinical potential, or those which are most likely to be effectively licenced. Thus, there is more pressure for inventions to be successful and provide a return, and consequently reduced risk taking within OUI. Technology transfer managers are less able to 'take a punt' on inventions which are exciting but have an unclear commercialisation route. This budget is being further strained by the increased number of Translational Funding Awards won by the university, grants for which OUI is obliged to maintain the IP for the duration of the project, without extra funds and irrespective of whether the invention is commercially viable. Because of this stretched budget and the increasing patent maintenance costs over time, OUI are under pressure to either cut projects earlier or not file them in the first instance.

In one way, OUI may have become ‘victims of their own success’, and a consequence of higher demand with a flat budget means dropping patents. Thus, when increasing awareness within the university it is important that the facilitating group has the capacity to handle any resulting increase in demand. This is important in considering how raising the profile for BD may impact on its ability to provide a service. Indeed, BD already described the need for more staff, both to nurture relationships with companies in the face of increasing company demand for collaborations, and in support roles to build databases and support BD managers in matching the best partners. With increased awareness of the group, this demand would be expected to increase further.

In contrast to BD and OUI, the perception within RS was that bottlenecks would not be improved by increasing funds or personnel, as the primary limiting factors was on waiting for responses from industrial partners and groups within the university.

5.2.4 Strategies

Considering the limiting steps and the contributing factors that maintain them, the strategic aims developed at the end of Chapter 4 can be refined to more effectively improve the activities of facilitating groups. These refined strategies are shown in Table 5.4.

Table 5.4 Updated strategic aims from Chapter 4.

Previous strategic aim	Refined strategic aim
Encourage and attract new researchers to engage with industry	1) Encourage and attract new researchers to engage with industry
Help connect an academic researcher with the right company and individual for their needs	2) Raise awareness of Business Development
Provide guidance on how to engage with industry and what to expect during collaboration	
Streamline the contracting process	3) Raise awareness of how to best engage with Research Services
	4) Champion the creation and use of pre-negotiated contracts that have had input from multiple companies.
Maintain IP until it can be licensed	5) Increase the patent budget for Oxford University Innovation OR Change incentive system for academics so they can patent later

5.2.4.1 Encourage and attract new researchers to engage with industry

Whilst finding ways of encouraging new researchers to engage with industry was not something that was covered explicitly in the data, members of both BD and OUI noted how they tend to draw from an existing pool of academic contacts, potentially overlooking other academics whose research may be more likely to result in collaboration. Thus, part of encouraging new researchers to collaborate (beyond changing incentives) may be to enable greater visibility of academic groups and research interests to OUI and BD, so that they can identify appropriate PIs when the opportunity for collaboration arises.

5.2.5.2 Raise awareness of Business Development

An explicit aim of the BD group is to act as an intermediary between an academic and a company, and as a group they are well connected with industry due to the formation of relationships. Their role directly addresses two of the previous strategic aims –aiding in navigation and providing guidance in collections. However, the resources held within BD do not seem to transfer to many PIs. Academics very rarely approach BD seeking an industry partner, and awareness of the group was low amongst PIs interviewed. This may be due to BD's poor visibility to academics within the division, and/or a poor understanding of how BD can facilitate collaboration. Raising awareness of BD and their role within the division is a potentially useful strategy to help academic navigate large and unfamiliar companies.

OUI provide an insight into how this awareness could be raised, and potentially, how new researchers could be encouraged to collaborate. OUI implemented several proactive internal marketing strategies, ensuring that members are available to be accessed, increasing their presence amongst departments and integrating technology transfer into education. These measures have proven to be effective for OUI, who consequently have

substantially increased their profile within departments over the past few years. Such strategies could be similarly beneficial in raising the awareness of BD who remain relatively unknown amongst academics. Furthermore, it is possible that BD could integrate themselves into the systems already implemented by OUI, for example by co-ordinating days at different hot desks and supplementing lectures that OUI present at.

However, as demonstrated by OUI, the resulting increase in demand placed on a group by such increased awareness can strain the group and result in negative experiences for academics. Therefore, when comparable internal marketing strategies are implemented in BD, a concurrent increase in staff might be warranted in anticipation of the increased work load.

Additionally, while BD may be providing an important role, they only provide it within MSD. Results from this study show that most industry funded projects in translational research at Oxford are 'T0' or early phase, and so the scope for supporting industrial collaboration extends beyond MSD, particularly into other bioscience based divisions, such as the Maths, Physical and Life Sciences division (MPLS). Thus, the role of BD could be expanded to encompass other divisions, or other measures should be implemented throughout the university to help navigate industry and provide guidance on collaboration. Such measures may include mentorship schemes, lectures on what to expect when working with industry and increasing the exchange of personnel between academia and industry through hot desking or exchange programs.

5.2.4.3 Raise awareness of how to best engage with Research Services

Academics were unaware of many factors surrounding contracting, including: a) the role of RS and how RS can help them in their research, b) the time point at which RS should be contacted, c) what information RS require when drafting a contract (and why), and d) the

cause of delays and negotiating 'sticking-points'. This lead to a frustration with RS, especially when delays were due to disagreements over IP and overheads, issues with which RS was seen to be 'out of touch' with academic interests.

Streamlining contracts was one of the main strategies suggested by academics (Sections 3.2.8 and 4.2.4.3). Interactions with RS suggest that one key bottleneck is in data gathering from academics which could potentially be improved by increasing academic awareness of how to engage with RS. In the past, RS have sent a *pro forma* to academics to facilitate the data gathering process providing checklists of the required information, however these were not seen to have been successful, returning 'yes/no' answers where academics just ticked the easiest option to ensure that the collaboration progressed quickly. This may be due to academics not seeing the relevance of such information, or understanding how this may impact them and their research.

Thus, broader educational strategies could be employed as outlined for BD, such as holding seminars, hot desking, and ensuring that academics know who the member of RS in their department is so that they can begin to establish relationships. While it could be argued that the details of the contracting process are irrelevant to academics, the data support the idea that an increase in such understanding speeds up contracts and improves collaboration experiences. Furthermore, providing an understanding of the negotiating pinch-points and the ways in which RS helps academics may further encourage understanding of the process and reduce the impact of external discussions between the PI and the group.

These results go some way to reconciling two apparently conflicting observations that arose from the initial survey (Chapter 3). Firstly, the observation that contracts and the lengthy contracting process, were a significant barrier to collaboration, and secondly, that the RS group that undertakes the contracting is very highly regarded by many PIs. The stark contrast in these two perspectives suggests that increasing the awareness of the

role of these facilitating groups within the academic community, and clarifying the proper way in which to interact with them, could greatly increase both the overall collaboration experience for academics and subsequent positive outcomes for all.

5.2.4.4 Champion the creation and use of pre-negotiated contracts that have had input from multiple companies.

As discussed in Section 5.2.3.2, one of the strategies devised as a result of the 2003 Lambert report was a set of pre-negotiated contracts for use in collaborations between academia and industry. While the uptake of these contracts has been low, there is still scope for such measures to be effective. RS highlighted that Lambert agreements were sometimes used in collaborations with GSK UK, the only company which actively participated in the development of the contracts. It is possible to suggest, based on the information provided, that if such 'Lambert agreements' were to be re-determined with input from more companies, in a way that is able to satisfy lawyers from different firms, then adoption rates may improve. This assertion is supported by the success of the Brunswick Agreements, which are widely used by the parties that contributed to their creation. If such pre-negotiated agreements were made, they would need the input of many companies and universities, and it may be the case that different tiers of contracts would be drawn (e.g. for different company sizes and circumstances). The agreements may need to be regularly updated and assigned some sort of authority or enforcement (in that they should only be deviated from in specific occasions). Therefore, one potential way forward would be to bring together the Russell Group of UK universities with an industry stakeholder such as the ABPI, who can petition its members over acceptable terms.

While there may be some instances where the use of such pre-negotiated contracts could cause the university to 'miss out' on a better deal structure than if they have negotiated from their ideal starting position, the corresponding savings in time and effort could greatly outweigh this if the university can increase the throughput of contracts. While the feasibility of this is not entirely clear, it does seem a logical way to reduce the second process bottleneck (Section 5.2.2.1), particularly when the points of contention are so predictable. Furthermore, the efforts of establishing these agreements may well be far less than the sum of its parts within each UK research institution.

The fact that contracting was identified as such a barrier to collaboration more than 12 years after the initial Lambert review was published is testament to the work that still needs to be done. However, in those 12 years the remit of the university has evolved, culminating in a 'cultural shift' in academia towards impact. Thus, while the efficacy of the 2003 Lambert reports was limited, as is often the case with industry, it may be that it was a case of the wrong timing. As universities increasingly prioritise the commercialisation of their research, and industry increasingly seek innovation in the face of looming patent cliffs (Caves et al., 1991), it may well be that the right time for these negotiations is now.

5.2.4.5. Increase the patent budget for Oxford University Innovation *OR* Change incentive system for academics so they can patent later

The barriers to OUI finding partners early enough are difficult for the university to influence, such as the opacity of industry concerning their research interests. However, providing more funding to OUI to expand their budget could be a way to allow members more time and flexibility to find an appropriate partner while maintaining patents. This would also allow academics to develop their research, such that it might be more

appealing to industry. However, in the face of cuts to government funding to universities this approach may not be feasible.

In which case, other steps may need to be taken to match up what academia produces with what industry wants. It is possible, that in response to the 'cultural shift' promoting and recognising broader 'impact' when assessing academic research (HEFCE, 2014b), there should be a corresponding shift in the way that academics' outputs are recognised and 'counted'. One of the reasons that OUI struggles to secure licensees is because the research isn't sufficiently developed to be appealing to industry. This could potentially be improved if academics were not under so much pressure to publish quickly, but, as in the US, could instead develop their research to the point where it stood a better chance of being patentable. In this case, recognising patents as important outputs and rewarding academics for both filing and licensing IP, could provide a complementary incentive structure to the existing system, allowing both applied and pure research to flourish.

5.3 Discussion

This analysis enables the following responses to the questions outlined in section 5.1:

- Study question 3a): What are the constraints under which facilitating groups within the University of Oxford operate?
- Study question 3b): How feasible is the implementation of identified strategies to improve collaboration?

In response to question 3a), this analysis shows that despite the distinct roles of RS, BD and OUI, these groups encounter overlapping challenges in their interactions with academia and industry. Additionally, the complaints levied against facilitating groups in Chapter 4 can be linked to identified limiting steps within the groups (negotiating pinch points, patent lapses and BD as low profile), and more generally to poor knowledge transfer within the university, difficulties working with industry, and limited resources within facilitating groups. This adds validity to the data presented in Chapter 4, as two different interview populations identify the same barriers to collaboration.

In response to question 3b), the feasibility and potential prioritisation of the strategies refined in Section 5.2.4 were assessed by the author, taking into consideration: The size and expected timing of impact, feasibility of implementation, likelihood of success, and level of resource deployment required. Universities should first seek to pursue strategies that can deliver high impacts on collaboration with minimal effort within short and medium-term timeframes. Concurrently, initial work into longer-term strategies should be pursued in conjunction with other research institutions and stakeholders, such as companies and the government. Raising awareness of RS and BD within the academic community were prioritised based on the delivery of high impact in the short-term and low resource deployment and associated risks.

Table 5.5 Author evaluation of strategies to improve collaboration

Strategy	Impact; (when)	Feasibility	Difficulty	Resource deployment	Priority	Comments and risks
Encourage and attract new researchers to engage with industry	Medium; medium-term	High	Easy	Low	6	More investigation needed into how best to encourage academics. Risks of overwhelming existing support systems. Risks of encouraging collaboration where not required or appropriate.
Raise awareness of Business Development within the university	High; short-term	High	Easy	Low	1	Easy to implement with potentially high impact on benefiting researchers. Risks of overwhelming support systems and damaging industry relationships.
Raise awareness of how to best engage with Research Services	High; short-term	High	Easy	Low	2	Low risk. Potential for difficulties in delivering key information.
Champion the creation and use of pre-negotiated contracts with input from multiple companies or industry stakeholders.	High; long-term	Medium	Hard	High	4	May require large amount of time from staff, diverting attention away from key activities. Uptake of contracts may still be low across companies. Public perception of seeming 'greedy' or partisan to industry needs.
Increase OUI's patent budget	Medium; short-term	High	Easy	Medium	3	Increased cost per patent, potential loss of income if patents remain unattractive to industry.
Provide an alternative incentive system within academia to enable researchers to delay publishing in pursuit of more robust patent data	Very high; very long-term	Medium	Hard	High	5	Long-term priority, involving input from multiple stakeholders. Addresses cultural differences or 'root cause' of the process difficulty of finding licensees. Risks of disrupting existing systems, creating unfavourable research environment with the potential for a two-tier system.

The use of mixed methods to address these research questions adds greater validity to conclusions drawn from results using qualitative or quantitative measures alone and the use of insights from multiple groups adds further weight to these findings, beyond what is explored in most analyses of academia-industry collaboration. This is especially true for Research Services and Business Development, groups which are not considered in the wider literature. The derivation of strategies from academics in the first instance is of limited utility due to their incomplete understanding of the collaboration process, and a practical implementation of such measures would be required to accurately determine their impact. Insight from industrial partners through interviews or questionnaires would have added an additional and interesting dimension to understanding the potential value and uptake of suggested strategies. Such participation was pursued, but data collection was not completed due to time constraints.

5.3.1 Summary

This chapter triangulates the findings from the previous chapters by providing an alternative perspective to the process of translation. Through this, many of the same issues were identified, strengthening the case for targeting these barriers. Existing groups within the university are already supporting some of the mechanisms to improve collaboration identified in this study, yet they are not being used to best effect. It is both heartening and disappointing that most of the systems that would facilitate collaboration already exist in some form within university infrastructure. Resolving the poor uptake of facilitating groups through internal marketing efforts similar to those in OUI should be amongst the top priorities for universities, who have already provided the 'tools' for collaboration, and must now teach academics how to use them.

Chapter 6: Discussion and Implications

6.1 Introduction

Translational research bridges the ‘gap’ between basic and applied research, and plays an important role in realising public benefit from research. Within translational medicine, the gap between discovery and product is particularly large due to the varied and specific skills and expertise required to conduct clinical trials, in addition to the large amounts of time and money required to bring therapeutics to market. This study considers the use of collaboration between academia and industry as a means of bridging this gap, and overcoming the ‘valley of death’ (Section 1.1.2).

Industry conduct clinical trials for their own, in-house research compounds, but these are often ‘me-too’ or addition-to-class drugs that, while increasing patient options, tend to offer at best incremental improvements in efficacy (Drews and Ryser, 1996). More innovative research occurs in academia, where the development of disruptive technologies such as monoclonal antibodies, cell and gene therapies have been pioneered and researched for years before companies were willing to invest in their development (Edelstein et al., 2007, Sheridan, 2011). However, without industry involvement, few academics have the necessary skills, regulatory expertise and resources to be able to develop and deliver drugs to patients, as testified by the high attrition rates in the transition from preclinical to clinical research. This is especially true for the most innovative, paradigm-shifting drugs, where the path to market, in terms of regulation and reimbursement, is both untrodden and unclear, and potential applications may not be immediately obvious (as was the case for monoclonal antibodies (Milstein, 2000)). It seems that academics have the ideas and innovations, and industry have the skills, expertise and resources to translate them. Thus, in an era increasingly moving towards

personalised medicine, it was my hypothesis that collaboration between academia and industry is important in ensuring the progression of academic innovations to patient benefit.

In order to investigate this hypothesis, a search of the literature was performed, revealing little prior research on collaboration in this area. Furthermore, while academic motivations, barriers and strategies had been considered in other fields, a specific investigation into translational research was warranted due to the heterogeneity of experiences across subjects, compounded with the added risk and complexities of clinical trials. Lastly, if the role of collaboration in translational medicine is as important as postulated, then strategies to improve this process should be considered. Thus, in order to examine these features, the following research questions were derived and investigated:

1. What is the current landscape of academia-industry collaboration in translational medicine at the University of Oxford?
2. What are the key barriers to collaboration in translational medicine, and to what extent do they impact the progress of collaborations?
3. What managerial and/or organisational strategies could be implemented to maximise industry-academia research collaboration?

The findings are contextualised within this chapter, beginning by responding to these research questions, discussing the limitations of the study and the validity of results, then subsequently discussing the implications of research findings for both government and university policy.

6.2 Key Findings and Response to Research Questions

6.2.1 Research Question 1: What is the current landscape of academia-industry collaboration in translational medicine at the University of Oxford?

Academics who collaborated with industry were more likely to be women and less likely to have professorial titles than the general population of PIs in MSD and MPLS. Most PIs (79%) received the majority of their industry funding for early phase or pre-clinical research (T0) (Section 3.2.4). This implies that in translational research industry are willing to fund much more nascent research than expected based on the literature, and may explain why most academics did not perceive 'basic science orientation of academic research' as a barrier to receiving funding.

Academics tended to work with industry in multiple different ways (88% of respondents had experience of more than one type of interaction, Section 3.2.5). Industrial sponsorship of investigator-led research was the most common type of collaboration, with 85% of academics having experience of this type of interaction, and tended to comprise a relatively high proportion of funding, 60%, for those receiving it. This implies that academics at the University of Oxford experience relatively high levels of autonomy in their research collaborations, and is in accord with other fields which highlight recent moves towards genuine collaboration over transactions. Also interesting was the high frequency (70%) but low proportion (10%) of funding received by academics for consulting activities. Further information on the temporality of the receipt of different types of funding could be used to identify a correlation between consulting activities and more intensive types of collaboration (e.g. investigator-led studies), and indicate whether this consulting is a 'gateway' activity to further industry funding. A lack of information on the importance of informal activities is a weakness of the study, which is perhaps a

reflection of the landscape of industry-funded academic research generally, rather than in this particular field.

The perceptions of positive and negative aspects of collaboration are broadly reflective of those found in the literature (Sections 3.2.3 and 3.2.6). Funding was frequently discussed as both a motivation and an advantage, and often in the context of a lack of alternative funding options, which may indicate a lack of satisfaction of academics with the existing funding system for translational medicine. Indeed, as highlighted in the advantages (Section 3.2.6), 63 academics described industry funding as being easier to obtain and manage than Research Council or charity funding, with some describing Research Councils as risk-averse and less willing to fund truly innovative research. Beyond funding, many academics mentioned the benefits of seeing their work translated and having access to resources and expertise. This indicates that for academics at Oxford industry play an important role in assisting in translation and supporting academic research, an assertion that is supported by the results from Section 4.2.2.

The pursuit of this research question afforded an insight into industry-funded academic translational research, comprising the first study investigating this topic, and the first to consider the stage of development of the research as an influencing factor in collaboration.

6.2.2 Research Question 2: What are the key barriers to collaboration in translational medicine, and to what extent do they impact the progress of collaborations?

Barriers were analysed based on whether they arose due to institutional or cultural factors. Overall, institutional barriers appear to be the limiting factor that is aggravating the collaboration experience for academics, with negotiation processes being the most

commonly encountered barriers across all academic sub-groups. Of course, while each barrier may be examined in turn, the links between them should not be discounted. In particular, a broader consideration indicates that barriers experienced at the institutional level are symptomatic of deeper cultural differences. For example, barriers such as disagreements over IP and freedom to publish likely manifest due to macro level factors such as differences attitudes towards data-sharing. Members of facilitating groups identified bottlenecks in each of their respective processes which supported the institutional barriers as perceived by academics. For facilitating groups, these barriers stemmed from a lack of internal resources, poor communication within the university or difficulties associated with working with industry.

The most prominent cultural barrier was due to the short-term orientation of industry research. However, academics have successfully managed this difficulty through the establishment of genuine relationships, either as a way of gaining advance notice on industry priorities or in terms of mitigating unpredictable changes in funding. Furthermore, an improved understanding of the broader contexts and drivers of industry was observed as leading to more positive collaboration experiences. This is because a deeper cultural understanding enabled sympathy for industrial positions, and also allowed the academic to mitigate predictable downsides, for example, by ensuring a more diverse funding portfolio to allow for sudden changes in industrial focus. The relationship between contextual understanding and positive experiences is also true for academics who had a better understanding of the constraints that facilitating groups operate within. Thus, while efforts to reduce process barriers (as described in this thesis), may provide faster relief of ‘symptoms’, longer-term the university should seek to minimise cultural barriers through increased exposure and trust building between academia and industry.

Differences in the barriers encountered by clinical and non-clinical academics were identified, which may be partially explained by both differences in academic sub-cultures and differences in industrial goals for the collaboration when working with each party.

6.2.3 Research Question 3: What managerial and/or organisational strategies could be implemented to maximise industry-academia research collaboration?

The final list of strategies is presented in Table 5.5. Based on input from academics and facilitating groups, these strategies both target institutional inefficiencies and seek to mitigate cultural differences between academia and industry. However, when examining these strategies there are two additional points to consider.

Firstly, some of the strategies identified concern increasing uptake of existing tools to aid collaboration (e.g. by raising awareness of facilitating groups). This is because even though the university has actively encouraged collaboration, for example by forming departments to facilitate it, there has not been a concurrent shift in academic culture and values towards working with industry. In this way, 'top-down' changes made at an institutional level can be ineffective at addressing wider cultural differences, and a more grass-roots approach may be required to bring about real change. Due to the variances between and within academic sub-cultures, it is likely that multiple measures will need to be implemented to achieve these strategic aims.

Secondly, while these strategies were devised in relation to potential action that could be taken by the University of Oxford, the barriers they seek to address are relevant beyond this single institution, and will require the participation of multiple stakeholders if they are to be successful. For example, establishing a set of widely adopted pre-negotiated contracts for collaboration will require the input of government departments, Research Councils, Charities, industry, and other universities.

6.3 Contributions

The analysis presented in this thesis support the initial hypothesis that collaboration between academia and industry accelerates the drug development process, and provide potential ways in which such activities can be supported. Additionally, this research seeks to contribute to the existing literature both empirically and theoretically.

6.3.1 Empirical contributions

This research constitutes the first study considering translational medicine as the primary field of investigation of collaboration. Academics in this field perceive industry to play a vital role in the translational ecosystem, funding innovative research projects that Research Councils fail to. This broadens existing knowledge on academia-industry collaboration and adds to the literature that identifies collaboration experiences as being different in different fields. Moreover, the data show how the experiences of academics differ depending on the nature of their research (as clinical or not), even when within a single field of research.

The study also adds to existing research through the creation of a new data set using self-reported data, allowing for the identification of features such as the phase of development of the research, which has not previously been studied. Through this, it was identified that most academics receive industry funding for very early stage research, which is perhaps surprising as such research is unlikely to provide a return on investment in the short- or even medium-term. Furthermore, by asking PIs directly a more in-depth analysis into different types of collaboration activities is possible. Previous research on collaboration at an individual level encompassed mainly demographic characteristics based on number of patents or spin-out companies formed per academic, despite these being relatively

uncommon collaboration activities (Agrawal and Henderson, 2002, Gulbrandsen and Smeby, 2005). The typology used in this research enables the consideration of a much wider range of more common mechanisms of collaboration, and in particular of joint research projects. This is important as ‘entrepreneurship’ activities such as forming spin-outs can be difficult to align with traditional academic activities, and require substantial effort and a unique skillset to accomplish. Conversely, collaboration through joint research programmes align with existing academic tasks, require less commitment, less risk, and allow for greater variation in research activities, potentially suiting a wider range of academics.

Finally, the information gained on the operations on the University of Oxford provide insight into why the university is performing so well. Further application of the survey developed in Chapter 3 could provide a comparative base to refine this understanding and expand this data set.

6.3.2 Theoretical contributions

This research shows how collaboration with industry is especially important in translational medicine, as the barrier to market entry of clinical trials makes it highly unlikely that academics will be able to develop their research without a company to provide funding, reagents, and regulatory guidance. These analyses increase our theoretical understanding of why academics collaborate with industry, acknowledging both the ‘pull’ of industry resources and the ‘push’ of the unwillingness of Research Councils to fund ‘risky’ research. This is interesting as it brings into question the assumption that collaboration with industry is an intrinsically ‘voluntary’ activity, suggesting that in some circumstances collaboration is a necessity to ensure the continuation of the research group.

This research highlights how the proximity of research to clinical trials impacts the collaboration experience for academics, and suggests potential causes for this both within the university and due to differences in industry goals for clinical and non-clinical projects.

The micro-meso-macro framework allows for the acknowledgement of the individual characteristics of researchers and the interaction this may have with their institutional environment and culture. For example, the impact that distinct subcultures within clinical and non-clinical research have on the collaborative experiences of the researcher can be delineated. Furthermore, the role of relationships between individuals in academia and industry were seen to improve cultural differences, in concurrence with existing research (Davenport et al., 1998)

This research also highlights a flaw in the system by which universities are encouraging technology transfer. If the patents being produced protect technologies that are insufficiently developed to be of interest to their prospective licensees then they are of limited use. Thus, further structural changes should occur to fully bridge academic output with industry input. This agrees with and expands the work of Lockett and Wright (2005), who question the role of the TTO if the university does not undergo wider structural changes to encourage academics to pursue entrepreneurial activities.

Finally, the inclusion of facilitating groups beyond technology transfer offices is unique, and provided a novel insight into the institutional environment of academics. Higher levels of awareness or engagement with RS and BD correlated with positive collaboration experiences. However, engagement with these groups seems to be driven by the academic themselves, their awareness and experience and the inclination to seek assistance. In this way, the individual PI is a key determinant of collaboration experience, as it dictates the extent to which they benefit from their institutional environment.

6.4 Limitations and future research

The findings from this study emphasise the crucial role of collaboration between academia and industry in delivering the most innovative therapeutic developments as quickly and safely as possible. Accordingly, these findings may have wider implications for both collaboration practice and healthcare policy (Section 6.5). However, as highlighted by Edwards (2000), the degree to which implications can be drawn from research is inextricably linked to the quality of the research and the trustworthiness of the findings. In order to evaluate and contextualise the truth and generalisability of research conclusions, it is important to acknowledge both the methodological and theoretical limitations of the study, and assess the validity of claims made in light of those limitations. This is also useful in highlighting potential directions for future research efforts. Validity is defined by Trochim and Donnelly (2001) as “the extent to which a given proposition, inference or conclusion approximates to the truth.” In assessing the validity of results from mixed methods research, it is prudent to consider both internal and external validity.

6.4.1 Internal validity

Internal validity concerns the truth of findings within their original context. The Cabinet Office, in conjunction with the National Centre for Social Research developed a comprehensive framework for assessing the credibility, rigour, and relevance of individual qualitative research studies based around 18 appraisal questions (Spencer et al., 2003). Using this framework, it is possible to assess the internal validity of this research study as it relates to four guiding principles:

1. *Contributory in advancing wider knowledge or understanding about policy, practice, theory or a particular substantive field.*

This research details the first empirical study on university-industry collaboration in translational research in the United Kingdom. Results generated as part of this thesis have the potential to inform research and innovation policies in both the United Kingdom and internationally.

This research develops on existing knowledge about the motivations, advantages, disadvantages, and barriers to collaboration, as well as providing novel insight into the types and phase of development of industry involvement in academic research, and strategies that might be employed to improve it. Furthermore, as the literature on collaboration transitions from a high-level organisational analysis to more focused analyses of individual perspectives, this research adds to the literature through developing understanding of the individual determinants of academics' industrial engagement.

The study setting selected for this research was The University of Oxford, a desirable setting due to its excellence among UK universities in demonstrating 'impact' (Oxford submitted the second highest number of impact case studies the 2014 REF, with 258 units of analysis (HEFCE, 2014)). However, while interesting as a standalone study, some institutional factors are difficult to consider without comparison with another setting. For example, information concerning the role of institutional prestige as separate to that of the academic excellence of individual PIs could yield interesting information on the nature of relationships. The usefulness of this study, and the theoretical framework guiding it, would increase were it to be repeated within another institution, and would be most useful when the academics' perceptions are linked to the institutional setting and the support systems therein.

2. *Defensible in design by providing a research strategy that can address the evaluative questions posed.*

The findings from this study contribute a more detailed empirical understanding of collaboration from the perspective of the university. This research was, as discussed in Chapter 2, designed as an exploratory study of academia-industry collaboration in translational medicine. For such an exploratory study, using a combination of qualitative and quantitative research methods and considering multiple perspectives within the university was a practical way to investigate both breadth and depth in collaboration, permitting an assessment of the application of existing concepts whilst also allowing for the emergence of new ones. Furthermore, as multiple groups were able to corroborate the existence of barriers to collaboration and the potential of strategies to remedy them, it suggests that these findings are a true reflection of the situation (as considered from a critical realist perspective) and appropriate targets for the pursuit of further research.

However, two design flaws of the study are as follows. Firstly, this study is limited only to PIs who have received *funding* from industry, neglecting other interactions that academics can have with industry that does not involve the transfer of funds. The literature does not suggest that such non-financial collaborations constitute the majority of academia-industry interactions (Louis et al., 1989, D'Este and Patel, 2007), and these were not considered in this analysis due to difficulties in defining the study population. Secondly, it is difficult to draw firm conclusions from analyses on the characteristics of researchers and research that receives financial support from industry due to a lack of information on academics within the university in general (i.e., if 80% of PIs within the University of Oxford are conducting T0 or early, pre-clinical stage research (Chapter 3), and 80% of industry funded projects are also at T0, then such context would provide a better scope for determining the important features of industry funded research).

Unfortunately, despite several attempts, it was not possible to obtain this data in the timeframe for this thesis, which also prevented the use of descriptive statistics to determine the significance of differences between Oxford PIs collaborating with industry and Oxford PIs in general. The findings must therefore be considered in relation to the participants included in the study, which limits the breadth of the results. Additionally, there are some concerns about the validity and reliability of self-reported data with a long recall period.

Furthermore, insight from industrial partners through interviews or questionnaires would have added an additional and interesting dimension to understanding the potential value and uptake of suggested strategies. Such participation was pursued, but data collection was not completed due to time constraints.

3. Rigorous in conduct through the systematic and transparent collection, analysis and interpretation of qualitative data.

This research study was conducted as systematically as possible by seeking, where reasonable, to recruit the complete study populations, as opposed to using sampling techniques, which may result in key experiences not being included in the study (Sections 2.3.1.1 and 2.3.2.2). Efforts were made to obtain a wide range of data, for example by using a high-profile member of the university to distribute the initial questionnaire email, and by individually and repeatedly contacting each of the academics who had volunteered for interview. This minimised the propensity for selection bias on the part of the researcher, while admittedly allowing for self-selection bias on the part of the participant, especially in the case of interviews (For example, those PIs that responded to surveys, and in particular that then went on to volunteer for interview, were likely a self-selecting group that wished to discuss their collaborations due to particularly positive or negative

experiences, which may present more extreme views than typical collaborating academics). Participant recruitment for the investigation into facilitating groups was less systematic due to gatekeeper restrictions (Section 2.3.3). This could limit the validity of the data collected due to the consideration of fewer viewpoints. However, where necessary interviewees were contacted for follow-up clarifications on several occasions, and the presence of multiple perceptions of a group (i.e. RS were discussed by academics, BD, OUI and RS themselves) afforded a degree of validation through participant triangulation, and ensured the clarity and accuracy of the viewpoints that were considered in the study. Furthermore, all data collection was conducted by a single researcher (the author), ensuring consistency across interviews and between groups. However, it does also render any potential biases of the researcher as particularly impactful. Where possible these biases were minimised by ensuring transparency in analysis and interpretation.

As stated previously, survey analysis of qualitative responses was conducted independently by two researchers (Section 2.3.1.4). Multiple perspectives at this stage were important as the themes formed from the questionnaire went on to form the basis of the analytical framework for both sets of interviews. However, due to the volume of data collected during interview stages, only the author (Natasha Davie) considered the data set in its entirety, with individual interview transcripts being sent to other researchers for consideration of the accuracy of findings. The link between the original data and analysis was designed to be as transparent as possible through the use of software packages such as NVivo which can link the themes identified to the original source. When working within the Excel spreadsheet during framework analysis, quotes were transferred with surrounding information for context, and original recordings and transcripts were consistently referred to, in order to ensure that themes were accurately reflecting the context. Both the NVivo analysis and Excel framework were reviewed by two other researchers to discuss and refine themes.

4. Credible in claim through offering well-founded and plausible arguments about the significance of the evidence generated.

This thesis aimed to enable the reader to evaluate the credibility of the claims made by providing relative supporting information in particular by linking analyses to the original data. However, in order to avoid listing vast quantities of raw data, direct quotes were only sparingly used. In this case, while the quotes provided a verbatim link to the source, arguably the credibility is still in question unless the reader pursues the original data. Nonetheless, it is my belief that the ready availability of the original data is reassuring in terms of the credibility of individual claims made, and adds credence when these findings were used to populate and refine the theoretical framework. Furthermore, the cumulative data collection and analysis process allowed for the review of previous data in the light of new findings, which can strengthen or weaken previous interpretations.

However, one aspect that does bring claims into question is the lack of inclusion of industry perspectives, in particular when considering the efficacy of strategies. Despite efforts to collect data in this area in conjunction with the Association of the British Pharmaceutical Industry, insufficient time and resources precluded the use of such data in this thesis. Thus, while the strategies suggested may be conducive to improvement from a university perspective, this may not be case from an industrial perspective, limiting the credibility of these measures as viable for improving collaboration.

Additionally, while the findings can be put in the context of the literature on collaboration in other fields, my position on translational research facing challenges distinct from those in other fields would have been strengthened by complementary data from different divisions within the university, to distinguish what is a result of the research being translational and what is due to other factors.

6.4.2 External Validity

External validity relates to the extent to which findings can be generalised to other settings, thus the more studies conducted in different settings the greater the external validity (Farrington, 2003). Efforts to replicate the survey outlined in Chapter 3 at other UK high education institutions ultimately failed due to limitations in time, resources, and access of the researcher. Consequently, caution is required when attempting to extrapolate the results to other contexts. Indeed, there are several key differences between the University of Oxford and other universities, not least in practical considerations such as the federal structure and size and number of facilitating groups, but also in more nebulous factors such as prestige afforded by an international reputation which, as discussed in Chapter 5, seems a tangible difference between Oxford and some other UK universities in attracting industrial collaboration.

In terms of establishing the extent of potential generalisability, given the qualitative nature of this research, the following limits must be taken into consideration. Firstly, the findings of this study are particular to the participants constituting it and their unique experiences of collaborations. All discussions of ongoing and past experiences are provided within the context of their perceptions at the time of participation. Therefore these findings should not be applied to all academic translational researchers collaborating within the UK for example, or with a comparable university such as the University of Cambridge, where similarities in global reputation and federal structure perhaps provide the most logical comparison (Minguillo and Thelwall, 2015). Secondly, these findings should not be applied to other departments or fields of research within the University of Oxford due to differences in numerous factors, such as social and cultural experiences and differing commercialisation routes. These findings may be generalizable in some ways, however, as external validity is relatively subjective and in each case a

judgement has to be made as to how similar the circumstances of the original research are compared with the current context.

6.5 Implications

The aim of this study was to improve understanding of how academia-industry collaboration occurs in translational medicine. This was achieved through the broad application of a survey instrument to collaborating academics, and in depth semi-structured interviews with academics and facilitating groups within the University of Oxford, with a focus on the barriers to collaboration and potential strategies to resolve them.

Accordingly, the first major practical contribution of the present research is that it provides empirical data on the experiences of academics collaborating in this field, the funding landscape they operate within, the reasons why they collaborate, and the costs they incur for doing so. This information is the first of its kind for this field, and adds to the growing literature on collaboration in other fields such as engineering and aerospace. Recounting these experiences enables policy-makers, university staff, companies, and Research Councils to design actions and tools based on academics' actual actions and experiences. For example, Research Councils could take note that academics have often already completed most of the research for which they are applying for funding, and use this to re-evaluate the way they consider projects. Other groups could derive similar implications from these research findings.

The importance of collaboration in drug development echoes throughout this thesis. If the government is to overcome the 'translational gap' it needs to facilitate structural changes in academic incentives, not only to reward new outputs but also to encourage the continuation of entrepreneurial researchers in academia. One potential way of doing this could be to expand the current impact measure under the research excellence framework

(REF) to better incorporate collaboration. For the purposes of the 2014 REF, impact was defined as ‘an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia’, however ‘impacts on research or the advancement of academic knowledge’ are excluded (HEFCE, 2011). The unanimous recognition that industry involvement is required for successful collaboration highlights the need for this definition to be expanded to encourage collaboration activities due to their potential to be impactful in the long-term, perhaps even in circumstances where the immediate benefit remains within academia.

Additionally, formation of genuine relationships was found to be a key way to improve collaboration experiences for all parties. These relationships can enhance experiences at both institutional and cultural levels, and were the only mechanism by which highly impactful barriers such as the high turnover of industry personnel and the propensity for sudden changes in industrial research focus were mitigated (Section 4.2.3). Genuine relationships underlie successful collaborations, therefore government strategies should enhance the exchange of personnel between academia and industry, re-affirming findings from the Dowling Review. In the case of Oxford, enhancing relationships between academics and facilitating groups may be a way of circumventing the initial need for relationships between the PI and the company, instead allowing the university to harness and develop existing relationships.

From a policy perspective, it seems clear that there is a need to tailor policies for university-industry collaboration to the specific characteristics of academics operating in different fields, and even within those fields when the projects pursued are of different natures. Practically, this implies that a range of different strategies would need to be employed to account for differences in individual characteristics between researchers, as differences in character, motivation, and research characteristics makes different PIs sensitive to different types of incentives and levels of support.

As individual attributes of academics and their research seem important in explaining institutional levels of collaboration, the creation and efforts of facilitating groups are of limited use unless their creation is backed up by academics willing to collaborate. Thus, the university needs to seek to make itself attractive to entrepreneurial academics, or change culture to encourage existing academics to collaborate. This may be one of the key advantages that Oxford has with relation to 'brand value' – academics are approached by industry, thus the need for academics to be able to 'see opportunity' and identify collaboration partners may be reduced.

Similarly, universities should seek to reward and recognise entrepreneurial behaviour if early career academics are to pursue these activities within academia (rather than leaving academic careers if these activities go unrecognised, or are disapproved of). However, previous researchers have highlighted how academics are motivated by the freedom to determine their own research topics and methods (Aghion et al., 2008, Stern, 2004). Prioritisation of industrial collaboration or commercially-relevant research may compromise this academic freedom. Therefore, in order to maintain this freedom whilst incentivising an appropriate balance between basic and applied research (and more broadly long term and short term research focus), it is important to establish clear rules of engagement for both academia and industry in collaboration. With this aim in mind, both government and university administrators should work together to establish regulations that guarantee academic independence and research autonomy irrespective of funding source.

Another implication for policy concerns the existing patenting system. In the UK, academic publication constitutes a novelty-destroying disclosure that precludes the ability of the inventor to patent that invention. This is not the case in the case in all countries, notably the USA, where a 'grace period' allows for patents to be filed up to 12 months after publication disclosure. Adopting such a measure in the UK could enable a

compromise between the currently conflicting needs for patents and publications by academia and industry, while providing greater consistency across borders for its researchers. Indeed, the primary users of the grace period in the US are academic groups. However, a 2015 report commissioned by the Intellectual Property Office comparing the US (12-month) and UK (non-existent) grace periods revealed that while academics in the UK were in favour of such a measure, British companies were not, seeing it as ambiguous and potentially leading to leaks in proprietary knowledge (IPO, 2015). However, this report only examined the use of patents in internal industrial R&D processes, and it may be the case that industrial attitudes would differ if presented with improvements to the quality of academic IP outputs as a result of such a grace period. On the other hand, while introducing a grace period or changing the incentive system in academia to allow translational academics to publish later is one approach, it is also pertinent to question why a drug will not be developed if it lacks IP patent protection. Is there a system beyond profits that could be harnessed to develop effective drugs whose patents have been dropped? Such questions are not simple, but may indicate a way to deliver value and recover innovations already swallowed by the 'valley of death'.

6.6 Conclusion

I started this research driven by a desire to find a better way to delivery cutting edge science to the patients that need it. I wanted to assess the feasibility of academia-industry interactions as a way to bridge the 'valley of death' and, as a result of this thesis, I believe that fostering such collaborations *do* represent a way to substantially improve the pathway from 'bench to bedside'.

However, there is room to question the status quo and challenge whether the prevailing paradigm is in fact optimum. Despite the lack of incentive for translation 31% of academics within MPLS and MSD had received industry funding for translational research, a substantial number, especially considering that this is likely an underestimate as it does not take into account non-financial collaborations. Furthermore, the PIs who participated in this study perceived working with industry as important for the translation of novel inventions into commercial products, so much so that many expressed the opinion that translation would be impossible without industry involvement (Section 4.2.2).

However, that academics perceive themselves as being unable to translate without industry is cause for concern. Several reasons were suggested to explain why academics did not perceive themselves as capable of full translation, and primarily these related to access to reagents, regulatory expertise and funding (Section 4.2.2). These resources are required due to the complexity of the decade-long, billion-dollar clinical trials process, arguably one of the longest and most expensive market authorisation processes, especially when accounting for the cost of failed drugs (DiMasi et al., 2016). Unfortunately, with the cost and time required to complete clinical trials, the question is - who would make that kind of investment?

While therapeutic interventions should be carefully regulated, it seems we have created a system where the only entities with sufficient resources to bring new innovations to market, and to do so repeatedly in the face of multiple failures, are 'Big Pharma'. Academics may perceive industry as crucial to translation because there is literally no other option. Alternative mechanisms to support academics traversing this process are lacking or not apparent, with academics seeking industry funding where risk-averse charities and Research Councils 'dry up', while the knowledge and broad expertise required to design and conduct trials are seen as housed primarily within industry.

The monopolisation of healthcare by commercial entities provides an environment of healthy competition amongst companies to produce the best drugs. However, when such companies are the only entities capable of delivering a drug throughout translation, this does provide some cause for concern, particularly when their primary incentive is the provision of shareholder value. This can incentivise unsavoury practices such as a lack of transparency over clinical trial data (Sim et al., 2006), the promotion of unproven off-label indications (Kesselheim et al., 2011), and the use of sophisticated and sometimes misleading marketing strategies to persuade medical professionals (Moynihan, 2008). Furthermore, these incentives can result in the reimbursement price of a new therapeutic being based on the maximum price the market will bear, rather than any reflection of its actual development costs or the benefits afforded to the patient. Industry play a vital role in bringing to market new drugs, and provide substantial public benefit in doing so, but if we are to give institutions such power in our system, it is in our best interests to ensure that such institutions are incentivised appropriately.

However, this still allows companies to select which research is developed. Academics are insufficiently supported in pursuing their research beyond their initial hypotheses. They are unable to pursue therapeutic interventions when the science is promising, but instead are limited to research which is perceived by industry as commercially viable. Thus, while

I am supportive of collaboration as a means to facilitate translation, I firmly believe that those academics who wish to translate their own research should be able to do so. If not a direct route from 'bench to bedside' within academia, the system should at least present an alternative route to translating with industry, such as a route to market irrespective of potential financial value, and a means to rescue innovations lost due to their lack of commercial viability.

The knowledge that industry are unlikely to develop products that are not patent protected is not new, however this research has highlighted the inefficiency with which potentially valuable patents frequently lapse and are never capitalised on. Thus, in addition to the strategies suggested with respect to the university, wider policy measures could be considered to correct incentives and level the playing field for academic groups and smaller companies. Such mechanisms include allowing patients earlier access to medicines through adaptive licensing schemes such as Medicines Adaptive Pathways to Patients (MAPPs), also enable smaller companies to complete trials without accumulating insurmountable debt (Eichler et al., 2015, Baird et al., 2014); reimbursing industry based on the effectiveness of their products through incorporating outcomes- or value-based pricing reimbursement models (Claxton et al., 2008, Danzon et al., 2015); and perhaps even facilitating the ethical lowering of regulatory boundaries (Goldman et al., 2015)(Salman et al., 2014). Such schemes could allow drugs to 'fail earlier', thereby reducing the costs of drugs for patients, and providing a platform from which academics can develop their research to the extent where there is a clearer path to commercialisation.

We have a system where academic innovations are not sufficiently developed to be picked up by a profit-motivated industry, and a new model is needed. As medicine and healthcare trend towards personalised applications, the halcyon days of the 'blockbuster' drug seem increasingly distant (Cutler, 2007). In the wake of Brexit, the UK has been presented with

an opportunity to re-evaluate substantial volumes of regulation. Through such reform, the model for drug development could be repurposed, providing the right incentives for all stakeholders, and radically improving the ways in which we deliver care.

References

- Statute XVI. Property, Contracts and Trusts, Part C: Authority to bind the University: 14.
- ABPI. 2014. *Industry/university collaborations in the UK* [Online]. Available: <http://www.abpi.org.uk/industry-info/knowledge-hub/randd/Pages/collaborations.aspx> [Accessed].
- ABPI 2016. ABPI Response to Lord Stern's Review of the Research Excellence Framework Association of the British Pharmaceutical Industry.
- ABRAMO, G., D'ANGELO, C. A., DI COSTA, F. & SOLAZZI, M. 2009. University-industry collaboration in Italy: A bibliometric examination. *Technovation*, 29, 498-507.
- ABRAMO, G., D'ANGELO, C. A. & MURGIA, G. 2013. Gender differences in research collaboration. *Journal of Informetrics*, 7, 811-822.
- ABRAMO, G., D'ANGELO, C. A. & MURGIA, G. 2014. Variation in research collaboration patterns across academic ranks. *Scientometrics*, 98, 2275-2294.
- AGHION, P., DEWATRIPONT, M. & STEIN, J. C. 2008. Academic freedom, private-sector focus, and the process of innovation. *The RAND Journal of Economics*, 39, 617-635.
- AGRAWAL, A. & HENDERSON, R. 2002. Putting Patents in Context: Exploring Knowledge Transfer from MIT. *Manage. Sci.*, 48, 44-60.
- ALEXANDER, A. 2009. RCUK/UUK Review of the Impact of Full Economic Costing on the UK Higher Education Sector. In: UK, R. C. & UK, U. (eds.). London.
- ALEXANDER, G. 2011. Seeding trials and the subordination of science: Comment on "study of neurontin: titrate to effect, profile of safety (steps) trial". *Archives of Internal Medicine*, 171, 1107-1108.
- AMABILE, T. M., PATTERSON, C., MUELLER, J., WOJCIK, T., KRAMER, S. J., ODOMIROK, P. W. & MARSH, M. 2001a. ACADEMIC-PRACTITIONER COLLABORATION IN MANAGEMENT RESEARCH: A CASE OF CROSS-PROFESSION COLLABORATION. *Academy of Management Journal*, 44.
- AMABILE, T. M., PATTERSON, C., MUELLER, J., WOJCIK, T., ODOMIROK, P. W., MARSH, M. & KRAMER, S. J. 2001b. Academic-practitioner collaboration in management research: A case of cross-profession collaboration. *Academy of Management Journal*, 44, 418-431.
- ANATAN, L. 2009. Managing Technology Transfer Through University - Industry Collaboration: A Literature Review
- ANDERSON, N. B. 1998. Levels of analysis in health science: A framework for integrating sociobehavioral and biomedical research. *Annals of the New York Academy of Sciences*, 840, 563-576.
- ANGUS, J. A. 1992. Symbiotic relationship between a research institute and a pharmaceutical company: the Baker Institute/Glaxo Australia story. *Clinical and experimental pharmacology & physiology*, 19, 67-71.
- ANKRAH, S. N., BURGESS, T. F., GRIMSHAW, P. & SHAW, N. 2013. Asking both university and industry actors about their engagement in knowledge transfer: What single-group studies of motives omit. *Technovation*, 33, 5065.
- AUTIO, E., HAMERI, A.-P. & NORDBERG, M. 1996. A framework of motivations for industry-big science collaboration: a case study. *Journal of Engineering and Technology Management*, 13, 301-314.
- BAILEY, K. 2008. *Methods of Social Research, 4th Edition*, Free Press.
- BAIRD, L. G., BANKEN, R., EICHLER, H. G., KRISTENSEN, F. B., LEE, D. K., LIM, J. C., LIM, R., LONGSON, C., PEZALLA, E. & SALMONSON, T. 2014. Accelerated access to innovative medicines for patients in need. *Clinical Pharmacology & Therapeutics*, 96, 559-571.
- BANAL-ESTAÑOL, A., JOFRE-BONET, M. & LAWSON, C. 2015. The double-edged sword of industry collaboration: Evidence from engineering academics in the UK. *Research Policy*, 44, 1160-1175.
- BARNES, T., PASHBY, I. & GIBBONS, A. 2002. Effective University - Industry Interaction:: A Multi-case Evaluation of Collaborative R&D Projects. *European Management Journal*, 20, 272-285.
- BAYES-BROWN, G. 2014. Putting tech transfer into perspective. *Global University Venturing*. UK.

- BEKKERS, R. & FREITAS, I. M. B. 2008. Analysing knowledge transfer channels between universities and industry: To what degree do sectors also matter? *Research policy*, 37, 1837-1853.
- BERCOVITZ, J. & FELDMAN, M. 2008. Academic Entrepreneurs: Organizational Change at the Individual Level. *Organization Science*, 19, 69-89.
- BERG, B. L. 2004. *Qualitative Research Methods for the Social Sciences*, Boston, Pearson.
- BERNDT, E. R. 2002. Pharmaceuticals in US health care: determinants of quantity and price. *The Journal of Economic Perspectives*, 16, 45-66.
- BIRNHOLTZ, J. P. 2007. When do researchers collaborate? Toward a model of collaboration propensity. *Journal of the American Society for Information Science and Technology*, 58, 2226-2239.
- BLUMENTHAL, D., CAUSINO, N., CAMPBELL, E. & LOUIS, K. S. 1996. Relationships between Academic Institutions and Industry in the Life Sciences — An Industry Survey. *New England Journal of Medicine*, 334, 368-374.
- BOARDMAN, P. C. & CORLEY, E. A. 2008. University research centers and the composition of research collaborations. *Research Policy*, 37, 900-913.
- BONACCORSI, A. & PICCALUGA, A. 1994. A theoretical framework for the evaluation of university-industry relationships. *R&D Management*.
- BRUNEEL, J., D'ESTE, P. & SALTER, A. 2010. Investigating the factors that diminish the barriers to university-industry collaboration. *Research Policy*, 39.
- BRYMAN, A. 1989. *Research Methods and Organization Studies*, Routledge.
- BRYMAN, A. & BELL, E. 2015. *Business Research Methods*, Oxford University Press.
- BUBELA, T., FITZGERALD, G. A. & GOLD, E. R. 2012. Recalibrating intellectual property rights to enhance translational research collaborations. *Science translational medicine*, 4.
- BUKVOVA, H. 2010. Studying research collaboration: a literature review. *Studying research collaboration: a literature review*.
- BUTLER, D. 2008. Translational research: crossing the valley of death. *Nature*, 453, 840-2.
- CALVERT, J. & PATEL, P. 2003. University-industry research collaborations in the UK: bibliometric trends. *Science and public policy*, 30, 85-96.
- CAVES, R. E., WHINSTON, M. D., HURWITZ, M. A., PAKES, A. & TEMIN, P. 1991. Patent expiration, entry, and competition in the US pharmaceutical industry. *Brookings papers on economic activity. Microeconomics*, 1991, 1-66.
- CH, T. R. H. T. L. H. O. T. 2012. No Stone Unturned: In Pursuit of Growth.
- CHAKRAVARTHY, R., COTTER, K., DIMASI, J., MILNE, C.-P. & WENDEL, N. 2016. Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy. *Therapeutic Innovation & Regulatory Science*, 1-10.
- CHEN, Y. & CHANG, K. 2010. The relationship between a firm's patent quality and its market value —
The case of US pharmaceutical industry. *Technological Forecasting & Social Change*, 77, 20-33.
- CHIN-DUSTING, J., MIZRAHI, J., JENNINGS, G. & FITZGERALD, D. 2005. Finding improved medicines: the role of academic-industrial collaboration. *Nature Reviews Drug Discovery*, 4, 891-897.
- CLARYSSE, B., WRIGHT, M., LOCKETT, A., VAN DE VELDE, E. & VOHORA, A. 2005. Spinning out new ventures: a typology of incubation strategies from European research institutions. *Journal of Business Venturing*, 20, 183-216.
- CLAXTON, K., BRIGGS, A., BUXTON, M. J., CULYER, A. J., MCCABE, C., WALKER, S. & SCULPHER, M. J. 2008. Value based pricing for NHS drugs: an opportunity not to be missed? *Bmj*, 336, 251-254.
- COCKBURN, I. M. & HENDERSON, R. M. 1998. Absorptive Capacity, Coauthoring Behavior, and the Organization of Research in Drug Discovery. *The Journal of Industrial Economics*, 46, 157-182.
- COHEN, L., MANION, L. & MORRISON, K. 2000. *Research Methods in Education*, Routledge.
- COHEN, W. M. & LEVINTHAL, D. A. 1989. Innovation and learning: the two faces of R & D. *The economic journal*, 99, 569-596.
- COHEN, W. M., NELSON, R. R. & WALSH, J. P. 2002. Links and Impacts: The Influence of Public Research on Industrial R&D. *Management Science*, 48, 1-23.
- CONGRESS, U. 1980. Bayh-Dole Act - Patent and Trademark Act Amendments. *Government of United States of America*.

- CONGRESS, U. 1984. Stevenson-Wydler Technology Innovation Act of 1980. *United States Code, Title, 15*, 3701-3714.
- CORREA, C. M. 2004. Ownership of knowledge--the role of patents in pharmaceutical R&D. *Bulletin of the World Health Organization*, 82, 784-790.
- CRESWELL, J. W. 2007. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*, SAGE Publications.
- CRESWELL, J. W. 2013. *Research design: Qualitative, quantitative, and mixed methods approaches*, Sage publications.
- CULLITON, B. J. 1983. Academe and industry debate partnership. *Science (New York)*.
- CUTLER, D. M. 2007. The demise of the blockbuster? *New England Journal of Medicine*, 356, 1292-1293.
- D'ESTE, P. & FONTANA, R. 2007. What drives the emergence of entrepreneurial academics? A study on collaborative research partnerships in the UK. *Research Evaluation*, 16, 257-270.
- D'ESTE, P. & IAMMARINO, S. 2010. The spatial profile of university-business research partnerships. *Papers in Regional Science*, 89, 335-350.
- D'ESTE, P. & PATEL, P. 2007. University-Industry linkages in the UK: What are the factors underlying the variety of interactions with industry? *Research Policy*.
- D'ESTE, P. & PATEL, P. 2007. University-industry linkages in the UK: What are the factors underlying the variety of interactions with industry? *Research Policy*, 36, 1295-1313.
- D'ESTE, P. & PERKMANN, M. 2011. Why do academics engage with industry? The entrepreneurial university and individual motivations. *The Journal of Technology Transfer*, 36, 316-339.
- DANZON, P., TOWSE, A. & MESTRE-FERRANDIZ, J. 2015. Value-Based Differential Pricing: Efficient Prices for Drugs in a Global Context. *Health economics*, 24, 294-301.
- DAUDT, H. M., VAN MOSSEL, C. & SCOTT, S. J. 2013. Enhancing the scoping study methodology: a large, inter-professional team's experience with Arksey and O'Malley's framework. *BMC Med Res Methodol*, 13, 48.
- DE CAMPOS, A. 2008. A review of the literature on university-industry links: towards an integrated approach in the study of influencing factors
- DEARING, R. 1997. National Committee of Inquiry into Higher Education. London.
- DIMASI, J. A., GRABOWSKI, H. G. & HANSEN, R. W. 2016. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*, 47, 20-33.
- DIVISION, U. O. O. M. S. 2015. *Innovation and Industry* [Online]. Available: <http://www.medsci.ox.ac.uk/support-services/innovation-industry> [Accessed 28th January 2016].
- DOCHERTY, D., EYTON, D., HUGHES, A., MARTIN, B., MINA, A., PEARCE, S. & PROBERT, J. 2014. Growing Value: Business-University Collaboration for the 21st Century. In: NCUB (ed.).
- DOWLING, A. 2015. The Dowling Review of Business-University Research Collaborations.
- DRAUGALIS, J. R. & COONS, S. J. 1995. Pharmacoeconomic research--facilitating collaboration among academic institutions, managed-care organizations, and the pharmaceutical industry: a conference report. *Clinical therapeutics*, 17, 89-108; discussion 88.
- DREWS, J. & RYSER, S. 1996. Innovation deficit in the pharmaceutical industry. *Drug Information Journal*, 30, 97-108.
- DROLET, B. C. & LORENZI, N. M. 2011. Translational research: understanding the continuum from bench to bedside. *Transl Res*, 157, 1-5.
- DYER, J. H. & SINGH, H. 1998. The relational view: Cooperative strategy and sources of interorganizational competitive advantage. *Academy of management review*, 23, 660-679.
- EASTERBY-SMITH, M., THORPE, R. & JACKSON, P. R. 2008. *Management Research*, SAGE.
- EC 1995. Green Paper on Innovation. In: COMMISSION, E. (ed.). Luxeburg.
- EDELSTEIN, M. L., ABEDI, M. R. & WIXON, J. 2007. Gene therapy clinical trials worldwide to 2007—an update. *The journal of gene medicine*, 9, 833-842.
- EDWARDS, T. 2000. 'All the Evidence Shows...': Reasonable expectations of educational research. *Oxford Review of Education*, 26, 299-311.
- EICHLER, H. G., BAIRD, L., BARKER, R., BLOECHL-DAUM, B., BØRLUM-KRISTENSEN, F., BROWN, J., CHUA, R., DEL SIGNORE, S., DUGAN, U. & FERGUSON, J. 2015. From adaptive licensing to

- adaptive pathways: Delivering a flexible life-span approach to bring new drugs to patients. *Clinical Pharmacology & Therapeutics*, 97, 234-246.
- EICHLER, H. G., KONG, S. X. & GREGOIRE, J. P. 2006. Outcomes research collaborations between third-party payers, academia, and pharmaceutical manufacturers: What can we learn from clinical research? *The European journal of health economics : HEPAC: health economics in prevention and care*, 7, 129-35.
- EISENHARDT, K. M. 1989. Building theories from case study research. *Academy of management review*, 14, 532-550.
- EPO. 2016. *The patenting process* [Online]. Available: <https://www.epo.org/learning-events/materials/inventors-handbook/protection/patents.html> [Accessed 30/08/2016].
- ETZKOWITZ, H. 2003. Research groups as 'quasi-firms': the invention of the entrepreneurial university. *Research Policy*, 32, 109-121.
- ETZKOWITZ, H., WEBSTER, A., GEBHARDT, C. & TERRA, B. R. C. 2000. The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm. *Research Policy*, 29, 313-330.
- FARRINGTON, D. P. 2003. Methodological quality standards for evaluation research. *The Annals of the American Academy of Political and Social Science*, 587, 49-68.
- FAULKNER, W. & SENKER, J. 1994. Making sense of diversity: public-private sector research linkage in three technologies. *Research Policy*, 23, 673-695.
- FINKIN, M. W. 1982. On institutional academic freedom. *Tex. L. Rev.*, 61, 817.
- FISHER, J. A. 2008. Institutional mistrust in the organization of pharmaceutical clinical trials. *Medicine, health care, and philosophy*, 11, 403-413.
- FONTANAROSA, P. B. & DEANGELIS, C. D. 2003. Translational medical research. *Jama*, 289, 2133-2133.
- FRANK, R. G. & SALKEVER, D. S. 1997. Generic entry and the pricing of pharmaceuticals. *Journal of Economics & Management Strategy*, 6, 75-90.
- FREY, B. B., LOHMEIER, J. H., LEE, S. W. & TOLLEFSON, N. 2006. Measuring collaboration among grant partners. *American Journal of Evaluation*, 27, 383-392.
- FRIEDMAN, J. & SILBERMAN, J. 2003. University technology transfer: do incentives, management, and location matter? *The Journal of Technology Transfer*, 28, 17-30.
- FURNHAM, A. 2012. *The Psychology of Behaviour at Work: The Individual in the Organization*, Taylor & Francis.
- GALE, N. K., HEATH, G., CAMERON, E., RASHID, S. & REDWOOD, S. 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13, 117.
- GEIGER, R. L. 2008. Corporate-Sponsored Research at Penn State: Report to the Office of the Vice President for Research.
- GIURI, P., MARIANI, M., BRUSONI, S., CRESPI, G., FRANCOZ, D., GAMBARDELLA, A., GARCIA-FONTES, W., GEUNA, A., GONZALES, R., HARHOFF, D., HOISL, K., LE BAS, C., LUZZI, A., MAGAZZINI, L., NESTA, L., NOMALER, O., PALOMERAS, N., PATEL, P., ROMANELLI, M. & VERSPAGEN, B. 2007. Inventors and invention processes in Europe: Results from the PatVal-EU survey. *Research Policy*, 36, 1107-1127.
- GLOSSARY, P. M. 2014. *Key Opinion Leader (KOL)* [Online]. Available: <http://www.pharmamkting.com/glossary/keyopinionleader.htm> [Accessed 1/08/2016].
- GOBO, G. & MAUCERI, S. 2014. Deviant Case Analysis: Improving (a posteriori) data quality. *Constructing Survey Data: An Interactional Approach*. SAGE.
- GOLDMAN, M., SEIGNEURET, N. & EICHLER, H.-G. 2015. The Innovative Medicines Initiative: an engine for regulatory science. *Nature Reviews Drug Discovery*, 14.
- GRABOWSKI, H. 2006. Patents and new product development in the pharmaceutical and biotechnology industries. In: SMITH, C. J. & O'DONNELL, J. T. (eds.) *The Process of new drug discovery and development*. London: Informa Healthcare.
- GREENHALGH, T. & FAHY, N. 2015. Research impact in the community-based health sciences: an analysis of 162 case studies from the 2014 UK Research Excellence Framework. *BMC medicine*, 13, 1.
- GRIMALDI, R., KENNEY, M., SIEGEL, D. S. & WRIGHT, M. 2011. 30 years after Bayh-Dole: Reassessing academic entrepreneurship. *Research Policy*, 40, 1045-1057.
- GUBA, E. G. & LINCOLN, Y. S. 1994. Competing paradigms in qualitative research. *Handbook of qualitative research*, 2, 105.

- GULBRANDSEN, M. & SMEBY, J.-C. 2005. Industry funding and university professors' research performance. *Research Policy*, 34, 932-950.
- HAEUSSLER, C. & COLYVAS, J. A. 2011. Breaking the ivory tower: academic entrepreneurship in the life sciences in UK and Germany. *Research Policy*, 40, 41-54.
- HALL, B., LINK, A. & SCOTT, J. 2001. Barriers inhibiting industry from partnering with universities: evidence from the advanced technology program. *The Journal of Technology Transfer*.
- HALL, B. H. 2004. University-industry research partnerships in the United States. European University Institute Badia Fiesolana,, San Domenico, Italy.
- HANNAH, D. R. & LAUTSCH, B. A. 2010. Counting in Qualitative Research: Why to Conduct it, When to Avoid it, and When to Closet it. *Journal of Management Inquiry*, 20, 14-22.
- HANSON, D. 2005. *CE Marking, Product Standards and World Trade*, Edward Elgar Publishing Limited.
- HARBIN, T. 2014. Industry has undue influence on academic collaboration and safeguards need strengthening: white coat... which hat. *Survey of ophthalmology*, 59, 346-8.
- HAUSER, H. 2010. The Current and Future Role of Technology and Innovation Centres in the UK.
- HAUSER, H. 2014. Review of the Catapult network
- HEFCE 2014a. Memorandum of assurance and accountability between HEFCE and institutions: Terms and conditions for payment of HEFCE grants to higher education institutions.
- HEFCE 2014b. REF 2014: The results. In: (HEFCE), H. E. F. C. F. E. (ed.).
- HEFCE 2015. The nature, scale and beneficiaries of research impact: An initial analysis of Research Excellence Framework (REF) 2014 impact case studies. In: SCIENCE, K. S. C. L. A. D. (ed.).
- HENNINK, M., HUTTER, I. & BAILEY, A. 2010. *Qualitative Research Methods*, SAGE Publications.
- HERTZFELD, H. R., LINK, A. N. & VONORTAS, N. S. 2006. Intellectual property protection mechanisms in research partnerships. *Research Policy*, 35, 825-838.
- HOUSE OF COMMONS, B., INNOVATION AND SKILLS COMMITTEE 2014. Business - University Collaboration.
- HOUSE OF COMMONS, S. A. T. C. 2013. Bridging the valley of death: improving the commercialisation of research.
- HUDSON, J. 2000. Generic take-up in the pharmaceutical market following patent expiry: A multi-country study. *International Review of Law and Economics*, 20, 205-221.
- INDUSTRY, W. I. A. A. 2001. Available: <http://www.the-scientist.com/?articles.view/articleNo/13331/title/Industry-vs-Academia/> [Accessed 8th June 2016].
- IPO 2010. Lambert toolkit: model research collaboration agreements. In: OFFICE, I. P. (ed.).
- IPO 2013. Collaborative Research between Business and Universities: The Lambert Toolkit 8 Years On. In: OFFICE, I. P. (ed.).
- IPO 2015. Patent Harmonisation: US & UK Study on Grace Periods. In: OFFICE, I. P. (ed.). London.
- IVASCU, L., CIRJALIU, B. & DRAGHICI, A. 2016. Business Model for the University-industry Collaboration in Open Innovation. *Procedia Economics and Finance*, 39, 674-678.
- JASSAWALLA, A. R. & SASHITTAL, H. C. 1998. An examination of collaboration in high-technology new product development processes. *Journal of product innovation management*, 15, 237-254.
- JESSON, J., MATHESON, L. & LACEY, F. M. 2011. *Doing Your Literature Review: Traditional and Systematic Techniques*, SAGE Publications.
- KAITIN, K. I. 2010. Deconstructing the Drug Development Process: The New Face of Innovation. *Clinical pharmacology and therapeutics*, 87, 356-361.
- KENNEY, M. & GOE, W. 2004. The role of social embeddedness in professorial entrepreneurship: a comparison of electrical engineering and computer science at UC Berkeley and Stanford. *Research Policy*, 33, 691-707.
- KESSELHEIM, A. S., MELLO, M. M. & STUDDERT, D. M. 2011. Strategies and practices in off-label marketing of pharmaceuticals: a retrospective analysis of whistleblower complaints. *PLoS Med*, 8, e1000431.
- KESSELHEIM, A. S., ROBERTSON, C. T., MYERS, J. A., ROSE, S. L., GILLET, V., ROSS, K. M., GLYNN, R. J., JOFFE, S. & AVORN, J. 2012. A Randomized Study of How Physicians Interpret Research Funding Disclosures. *New England Journal of Medicine*, 367, 1119-1127.

- KESSLER, D. A., ROSE, J. L., TEMPLE, R. J., SCHAPIRO, R. & GRIFFIN, J. P. 1994. Therapeutic-Class Wars -- Drug Promotion in a Competitive Marketplace. *New England Journal of Medicine*, 331, 1350-1353.
- KNELLER, R., MONGEON, M., COPE, J., GARNER, C. & TERNOUTH, P. 2014a. Industry-university collaborations in Canada, Japan, the UK and USA--with emphasis on publication freedom and managing the intellectual property lock-up problem. *PloS one*, 9.
- KNELLER, R., MONGEON, M., COPE, J., GARNER, C. & TERNOUTH, P. 2014b. Industry-university collaborations in Canada, Japan, the UK and USA--with emphasis on publication freedom and managing the intellectual property lock-up problem. *PLoS One*, 9, e90302.
- KOCK, N., AUSPITZ, C. & KING, B. 2000. Using the web to enable industry-university collaboration: an action research study of a course partnership. *Informing Science*, 3, 157-165.
- KONECNY, E., QUINN, C., SACHS, K. & THOMPSON, D. 1995. *Universities and industrial research*, Royal Society of Chemistry.
- KULEJ, M. 2007. *Surveys in HE – methodology and design*, London, Camden Lock.
- LAMBERT, R. 2003a. Lambert review of business-university collaboration: Final report. *University of Illinois at Urbana-Champaign's Academy, Åŕ*.
- LAMBERT, R. 2003b. Lambert Review of Business-University Collaboration: Final Report.
- LANGLEY, A. 1999. Strategies for theorizing from process data. *Academy of Management review*, 24, 691-710.
- LAURSEN, K., REICHSTEIN, T. & SALTER, A. 2011. Exploring the Effect of Geographical Proximity and University Quality on University–Industry Collaboration in the United Kingdom. *Regional Studies*, 45, 507-523.
- LAURSEN, K. & SALTER, A. 2004. Searching high and low: what types of firms use universities as a source of innovation? *Research Policy*, 33, 1201-1215.
- LEBEAU, L.-M., LAFRAMBOISE, M.-C., LARIVIÈRE, V. & GINGRAS, Y. 2008. The effect of university–industry collaboration on the scientific impact of publications: the Canadian case, 1980–2005. *Research Evaluation*, 17, 227-232.
- LEE, Y. S. 2000. The Sustainability of University-Industry Research Collaboration: An Empirical Assessment. *The Journal of Technology Transfer*, 25, 111-133.
- LINDELÖF, P. & LÖFSTEN, H. 2004. Proximity as a Resource Base for Competitive Advantage: University–Industry Links for Technology Transfer. *The Journal of Technology Transfer*, 29, 311-326.
- LINK, A. N., SIEGEL, D. S. & BOZEMAN, B. 2007. An empirical analysis of the propensity of academics to engage in informal university technology transfer. *Industrial and corporate change*, 16, 641-655.
- LITTELL, R., HENRY, P. & AMMERMAN, C. 1998. Statistical analysis of repeated measures data using SAS procedures. *Journal of animal science*, 76, 1216-1231.
- LITTEN, R. Z., RYAN, M., FALK, D. & FERTIG, J. 2014. Alcohol Medications Development: Advantages and Caveats of Government/Academia Collaborating with the Pharmaceutical Industry. *Alcoholism: Clinical and Experimental Research*, 38, 1196-1199.
- LÓPEZ-MARTÍNEZ, R., MEDELLIN, E., SCANLON, A. & SOLLEIRO, J. 1994. Motivations and obstacles to university industry cooperation (UIC): a Mexican case. *R&D Management*, 24, 017-030.
- LU, M., SAFREN, S. A., SKOLNIK, P. R., ROGERS, W. H., COADY, W., HARDY, H. & WILSON, I. B. 2008. Optimal recall period and response task for self-reported HIV medication adherence. *AIDS and Behavior*, 12, 86-94.
- MACK, J. 2015. A KOL by Any Other Name: Too Toxic for Everyday Use, or Still the Best Term to Use? *Pharma Marketing News*.
- MAGLAUGHLIN, K. L. & SONNENWALD, D. H. Factors that impact interdisciplinary natural science research collaboration in academia. Proceedings of the ISSI, 2005. Citeseer, 24-25.
- MANSFIELD, E. 1998. Academic research and industrial innovation: An update of empirical findings. *Research Policy*, 26, 773-776.
- MARKMAN, G. D. & SIEGEL, D. S. 2008. Research and technology commercialization. *Journal of Management, Åŕ*.
- MARKMAN, G. D., SIEGEL, D. S. & WRIGHT, M. 2008. Research and technology commercialization. *Journal of Management Studies*, 45, 1401-1423.
- MCCLELLAN, R. O. 1999. Openness in private-public collaboration. *Science*, 284, 1124.

- MCKELVEY, M. & HOLMÉN, M. 2010. *Learning to compete in European universities: From social institution to knowledge business*, Edward Elgar Publishing.
- MCNULTY, T. & FERLIE, E. 2002. *Reengineering Health Care: The Complexities of Organizational Transformation*, OUP Oxford.
- MEFFERT, J. J. 2009. Key opinion leaders: where they come from and how that affects the drugs you prescribe. *Dermatol Ther*, 22, 262-8.
- MELIN, G. 2000. Pragmatism and self-organization: Research collaboration on the individual level. *Research policy*, 29, 31-40.
- MELIN, G. & PERSSON, O. 1996. Studying research collaboration using co-authorships. *Scientometrics*, 36, 363-377.
- MERTON, R. K. 1973. *The sociology of science: Theoretical and empirical investigations*, University of Chicago press.
- MESSERLIN, P. A. 2001. *Measuring the Costs of Protection in Europe: European Commercial Policy in the 2000s*, Institute for International Economics.
- MEYER, M. 2006. Are patenting scientists the better scholars?. An exploratory comparison of inventor-authors with their non-inventing peers in nano-science and technology. *Research Policy*, 35, 1646-1662.
- MEYER-KRAHMER, F. & SCHMOCH, U. 1998. Science-based technologies: university-industry interactions in four fields. *Research Policy*.
- MILNE, C.-P. & MALINS, A. 2013. Academic-Industry Partnerships for Biopharmaceutical Research & Development: Advancing Medical Science in the U.S.: Tufts Center for the Study of Drug Development, Tufts University School of Medicine, Boston, MA.
- MILSTEIN, C. 2000. With the benefit of hindsight. *Immunology Today*, 21, 359-364.
- MINGUILLO, D. & THELWALL, M. 2015. Research excellence and university-industry collaboration in UK science parks. *Research Evaluation*, 24, 181-196.
- MINGUILLO, D., TIJSEN, R. & THELWALL, M. 2015. Do science parks promote research and technology? A scientometric analysis of the UK. *Scientometrics*, 102, 701-725.
- MITTLEMAN, B., NEIL, G. & CUTCHER-GERSHENFELD, J. 2013. Precompetitive consortia in biomedicine, how are we doing? *Nature biotechnology*, 31.
- MOLINA, A., PEIRE, J., CASTRO, M., CIGARRAN, J. M. & DE MORA, C. 1997. The Nature and Effectiveness of Industry-University Collaboration. . ESPRIT Project
- OMI-HEART (D1.3/1).
- MOTOHASHI, K. & MURAMATSU, S. 2012. Examining the university industry collaboration policy in Japan: Patent analysis. *Technology in Society*, 34, 149-162.
- MOWERY, D. C., NELSON, R. R., SAMPAT, B. N. & ZIEDONIS, A. A. 2001. The growth of patenting and licensing by US universities: an assessment of the effects of the Bayh-Dole act of 1980. *Research policy*, 30, 99-119.
- MOYNIHAN, R. 2008. Key opinion leaders: independent experts or drug representatives in disguise? *BMJ*, 336, 1402-1403.
- MSD. 2016a. *Introduction to Business Development* [Online]. Available: <https://www.medsci.ox.ac.uk/support-services/teams/innovation-industry/business-development/introduction-to-business-development> [Accessed 13/06/2016].
- MSD. 2016b. *Introduction to Business Development* [Online]. Available: <https://www.medsci.ox.ac.uk/support-services/teams/innovation-industry/business-development/introduction-to-business-development> [Accessed 02/08/2016].
- MUELLER, P. 2006. Exploring the knowledge filter: How entrepreneurship and university-industry relationships drive economic growth. *Research Policy*, 35, 1499-1508.
- MURRAY, F. 2004. The role of academic inventors in entrepreneurial firms: Sharing the laboratory life. *Research Policy*, 33, 643-659.
- NATHAN, C. 2007. Aligning pharmaceutical innovation with medical need. *Nat Med*, 13, 304-308.
- NCUB 2012. Enhancing Value Task Force: Series of Reports.
- NELSON, A. J. 2009. Measuring knowledge spillovers: What patents, licenses and publications reveal about innovation diffusion. *Research Policy*, 38, 994-1005.
- NELSON, R. R. 2001. Observations on the post-Bayh-Dole rise of patenting at American universities. *The journal of Technology transfer*, 26, 13-19.
- NOCRI 2015. Growth through Health Research: The NIHR as an engine for growth. . In: (NOCRI), N. O. F. C. R. I. (ed.).
- OLIVER, C. 1990. Determinants of interorganizational relationships: Integration and future directions. *Academy of management review*, 15, 241-265.

- OUI 2013. Annual Report.
- OUI 2015. Annual Report.
- OUI. 2016a. *About Isis Innovation* [Online]. Available: <http://isis-innovation.com/about/> [Accessed 13/6/2016].
- OUI 2016b. Intellectual Property, Patents and Licences. In: NAYLOR, L. (ed.).
- OUI. 2016c. *Medical Sciences and Oxford University Innovation* [Online]. Available: <http://innovation.ox.ac.uk/university-members/medical-sciences-innovation/> [Accessed 25/08/16].
- OWEN-SMITH, J. & POWELL, W. W. 2003. The expanding role of university patenting in the life sciences: assessing the importance of experience and connectivity. *Research Policy*, 32, 1695-1711.
- OXFORD, U. O. 2012. *Strategic plan 2013-18* [Online]. Available: <https://www.ox.ac.uk/about/organisation/strategic-plan?wssl=1> [Accessed 8th June 2016].
- PALMER, E. 2012. *Top 10 pharma companies by employees* [Online]. Fierce Pharma. Available: <http://www.fiercepharma.com/special-report/top-10-pharma-companies-by-employees> [Accessed 04/08/2016].
- PAPADAKI, M. & HIRSCH, G. 2013. Curing consortium fatigue. *Science translational medicine*, 5.
- PARTHA, D. & DAVID, P. A. 1994. Toward a new economics of science. *Research Policy*, 23, 487-521.
- PATRIDGE, E. V., GAREISS, P. C., KINCH, M. S. & HOYER, D. W. 2015. An analysis of original research contributions toward FDA-approved drugs. *Drug discovery today*, 20, 1182-1187.
- PATTON, Q. 2002. *Qualitative Evaluation and Research Methods*.
- PERKMANN, M., TARTARI, V., MCKELVEY, M., AUTIO, E., BROSTROM, A., D'ESTE, P., FINI, R., GEUNA, A., GRIMALDI, R., HUGHES, A., KRABEL, S., KITSON, M., LLERENA, P., LISSONI, F., SALTER, A. & SOBRERO, M. 2013a. Academic engagement and commercialisation: A review of the literature on university-industry relations. *Research Policy*, 42.
- PERKMANN, M., TARTARI, V., MCKELVEY, M., AUTIO, E., BROSTROM, A., D'ESTE, P., FINI, R., GEUNA, A., GRIMALDI, R., HUGHES, A., KRABEL, S., KITSON, M., LLERENA, P., LISSONI, F., SALTER, A. & SOBRERO, M. 2013b. Academic engagement and commercialisation: A review of the literature on university-industry relations. *Research Policy*, 42.
- PERKMANN, M. & WALSH, K. 2007. University-industry relationships and open innovation: Towards a research agenda. *International Journal of Management Reviews*, 9, 259-280.
- PERTUZÉ, J., CALDER, E., GREITZER, E. & LUCAS, W. 2010. Best Practices for Industry-University Collaboration. *MIT Sloan Management Review*, 51, 82-90.
- PHAM, M. T., RAJIC, A., GREIG, J. D., SARGEANT, J. M., PAPADOPOULOS, A. & MCEWEN, S. A. 2014. A scoping review of scoping reviews: advancing the approach and enhancing the consistency. *Res Synth Methods*, 5, 371-85.
- PINCUS, H. A. 2009. Challenges and pathways for clinical and translational research: why is this research different from all other research? *Academic medicine : journal of the Association of American Medical Colleges*, 84, 411-412.
- PIRNAY, F., SURLEMONT, B., NLEMVO, F., X00E, X00E & RIC 2003. Toward a Typology of University Spin-offs. *Small Business Economics*, 21, 355-369.
- PONDS, R., VAN OORT, F. & FRENKEN, K. 2007. The geographical and institutional proximity of research collaboration. *Papers in regional science*, 86, 423-443.
- POYAGO-THEOTOKY, J., BEATH, J. & SIEGEL, D. S. 2002. Universities and Fundamental Research: Reflections on the Growth of University-Industry Partnerships. *Oxford Review of Economic Policy*, 18 10-21.
- PRONK, J. T., LEE, S. Y., LIEVENSE, J., PIERCE, J., PALSSON, B., UHLEN, M. & NIELSEN, J. 2015a. How to set up collaborations between academia and industrial biotech companies. *Nat Biotechnol*, 33, 237-40.
- PRONK, J. T., LEE, S. Y., LIEVENSE, J., PIERCE, J., PALSSON, B., UHLEN, M. & NIELSEN, J. 2015b. How to set up collaborations between academia and industrial biotech companies. *Nat Biotech*, 33, 237-240.
- RAHM, D., KIRKLAND, J. & BOZEMAN, B. 2000. A Description of University-Industry R&D Collaboration in the United States. *University-Industry R&D Collaboration in the United States, the United Kingdom, and Japan*. Dordrecht: Springer Netherlands.

- RAPPERT, B., WEBSTER, A. & CHARLES, D. 1999. Making sense of diversity and reluctance: academic-industrial relations and intellectual property. *Research Policy*, 28, 873-890.
- RASMUSSEN, N. 2004. The moral economy of the drug company-medical scientist collaboration in interwar America. *Social studies of science*, 34, 161-85.
- ROESSNER, J. D., CHENEY, D. W. & COWARD, H. R. 2004. The Impact on Industry of Interaction with Engineering Research Centers. SRI International.
- ROTHAERMEL, F. T., AGUNG, S. D. & JIANG, L. 2007. University entrepreneurship: a taxonomy of the literature. *Industrial and Corporate Change*, 16, 691-791.
- RUBIN, H. J. & RUBIN, I. S. 2012. *Qualitative Interviewing: The Art of Hearing Data*, SAGE Publications.
- SALMAN, R. A.-S., BELLER, E., KAGAN, J., HEMMINKI, E., PHILLIPS, R. S., SAVULESCU, J., MACLEOD, M., WISELY, J. & CHALMERS, I. 2014. Increasing value and reducing waste in biomedical research regulation and management. *The Lancet*, 383, 176-185.
- SALTER, A. 2009. The changing nature of barriers to university-industry collaboration in the UK. Imperial College London Innovation Research Centre.
- SANDIESON, R. & L., K. J. 2010. Harnessing the power of education research databases with the pearl-harvesting methodological framework for information retrieval. *Journal of Special Education*.
- SANDIESON, R. W. & KIRKPATRICK, L. C. 2010. Harnessing the power of education research databases with the pearl-harvesting methodological framework for information retrieval. *Journal of Special Education*.
- SCANNELL, J. W., BLANKLEY, A., BOLDON, H. & WARRINGTON, B. 2012. Diagnosing the decline in pharmaceutical R&D efficiency. *Nat Rev Drug Discov*, 11, 191-200.
- SCHARTINGER, D., RAMMER, C., FISCHER, M. & FROHLICH, J. 2002. Knowledge interactions between universities and industry in Austria: sectoral patterns and determinants. *Research Policy*, 31, 303-328.
- SCHARTINGER, D., SCHIBANY, A. & GASSLER, H. 2001. Interactive Relations Between Universities and Firms: Empirical Evidence for Austria. *The Journal of Technology Transfer*, 26, 255-268.
- SCHERER, F. M. 2000. Patents and pharmaceutical innovation: The unusual importance of drug patents. In: CULYER, A. J. & NEWHOUSE, J. P. (eds.) *Handbook of Health Economics*. Elsevier Science B.V.
- SCHWARZ, N. & OYSEMAN, D. 2001. Asking questions about behavior: Cognition, communication, and questionnaire construction. *American Journal of Evaluation*, 22, 127-160.
- SEIDMAN, I. 2013. *Interviewing as qualitative research: A guide for researchers in education and the social sciences*, Teachers college press.
- SERVICES, U. O. O. A. 2016. *About research support at Oxford* [Online]. Available: <http://www.admin.ox.ac.uk/researchsupport/about/-d.en.33743> [Accessed 15/4/2016].
- SHERIDAN, C. 2011. Gene therapy finds its niche. *Nature biotechnology*, 29, 121-128.
- SIEGEL, D. S., WALDMAN, D. & LINK, A. 2003a. Assessing the impact of organizational practices on the relative productivity of university technology transfer offices: an exploratory study. *Research Policy*, 32, 27-48.
- SIEGEL, D. S., WALDMAN, D. A., ATWATER, L. E. & LINK, A. N. 2003b. Commercial knowledge transfers from universities to firms: improving the effectiveness of university-industry collaboration. *The Journal of High Technology Management Research*, 14, 111-133.
- SIEGEL, D. S., WALDMAN, D. A., ATWATER, L. E. & LINK, A. N. 2003c. Commercial knowledge transfers from universities to firms: improving the effectiveness of university-industry collaboration. *The Journal of High Technology Management Research*, 14, 111-133.
- SIEGEL, D. S., WALDMAN, D. A., ATWATER, L. E. & LINK, A. N. 2003d. Commercial knowledge transfers from universities to firms: improving the effectiveness of university-industry collaboration. *The Journal of High Technology Management Research*, 14, 111-133.
- SIEGEL, D. S., WALDMAN, D. A., ATWATER, L. E. & LINK, A. N. 2003e. Commercial knowledge transfers from universities to firms: improving the effectiveness of university-industry collaboration. *The Journal of High Technology Management Research*, 14, 111-133.
- SIEGEL, D. S., WALDMAN, D. A., ATWATER, L. E. & LINK, A. N. 2004. Toward a model of the effective transfer of scientific knowledge from academicians to practitioners: qualitative

- evidence from the commercialization of university technologies. *Journal of engineering and technology management*, 21, 115-142.
- SILVERMAN, D. 2010. *Qualitative research*, Sage.
- SILVERMAN, D. 2016. *Qualitative research*, Sage.
- SIM, I., CHAN, A.-W., GÜLMEZOĞLU, A. M., EVANS, T. & PANG, T. 2006. Clinical trial registration: transparency is the watchword. *The Lancet*, 367, 1631-1633.
- SIMARD, C. & WEST, J. 2006. Knowledge Networks and the Locus of Innovation. In: CHESBROUGH, H., VANHAVERBEKE, W. & WEST, J. (eds.) *Open Innovation: Researching a New Paradigm*. OUP Oxford.
- SMITH, R., GÖTZSCHE, P. C. & GROVES, T. 2014. Should journals stop publishing research funded by the drug industry? *Bmj*, 348, g171.
- SONNENWALD, D. H. 2007. Scientific collaboration. *Annual Review of Information Science and Technology*, 41, 643-681.
- SPENCER, L., RITCHIE, J., LEWIS, J. & DILLON, L. 2003. Quality in qualitative evaluation: a framework for assessing research evidence.
- SRIVASTAVA, A. & THOMSON, S. B. 2009. Framework Analysis: A Qualitative Methodology for Applied Policy Research. *The Journal of Administration & Governance*, 4, 72-79.
- STEPTOE, A., FREEDLAND, K., JENNINGS, J. R., LLABRE, M. M., MANUCK, S. B. & SUSMAN, E. J. 2010. *Handbook of Behavioral Medicine: Methods and Applications*, Springer New York.
- STERN, L. 2016. Research Excellence Framework (REF) review: Building on success and learning from experience.
- STERN, S. 2004. Do Scientists Pay to Be Scientists? *Manage. Sci.*, 50, 835-853.
- STEWART, G., LIBRARY, B., TECHNOLOGY, B. L. S. & BUSINESS 1999. *The Partnership Between Science and Industry: Co-Operation Or Conflict of Interest?*, British Library.
- STOCK, G. & HABENICHT, U. F. 1999. Collaboration between industry and academia--prospects for male fertility control. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics*, 67 Suppl 2, S85-92.
- SUNG, N. S., CROWLEY, W. F., JR., GENEL, M., SALBER, P., SANDY, L., SHERWOOD, L. M., JOHNSON, S. B., CATANESE, V., TILSON, H., GETZ, K., LARSON, E. L., SCHEINBERG, D., REECE, E. A., SLAVKIN, H., DOBS, A., GREBB, J., MARTINEZ, R. A., KORN, A. & RIMOIN, D. 2003. Central challenges facing the national clinical research enterprise. *JAMA*, 289, 1278-87.
- SUPPORT, U. O. O. R. 2014. *Introduction and background to FEC* [Online]. Available: <https://www.admin.ox.ac.uk/researchsupport/costing/intro/> [Accessed 3/8/2016].
- SUSSMAN, S., VALENTE, T. W., ROHRBACH, L. A., SKARA, S. & PENTZ, M. A. 2006. Translation in the health professions converting science into action. *Evaluation & the Health Professions*, 29, 7-32.
- TARTARI, V., SALTER, A. & D'ESTE, P. 2012. Crossing the Rubicon: exploring the factors that shape academics' perceptions of the barriers to working with industry. *Cambridge journal of economics*, 36, 655-677.
- TCC 2014. Public benefit: rules for charities. In: COMMISSION, T. C. (ed.).
- THE 2015. World University Rankings: Clinical, pre-clinical and health Times Higher Education
- THE 2016. World University Rankings. Times Higher Education
- THURSBY, J. G., JENSEN, R. & THURSBY, M. C. 2001. Objectives, characteristics and outcomes of University Licensing: A survey of major U.S. Universities. *Journal of Technology Transfer*, 26, 59-72.
- THURSBY, J. G. & KEMP, S. 2002. Growth and productive efficiency of university intellectual property licensing. *Research Policy*, 31, 109-124.
- TIJSEN, R. J. 2011. Joint research publications: A performance indicator of university-industry collaboration. *Evaluation in Higher Education*, 12, 19-40.
- TROCHIM, W. M. & DONNELLY, J. P. 2001. Research methods knowledge base.
- TROTMAN, R. E. 1987. Industry—an NHS perspective. *Journal of Medical Engineering & Technology*, 11, 220-223.
- TURVILLE, L. S. O. 2007. The Race to the Top: A Review of Government's Science and Innovation Policies.
- UAS 2008. Task Force on Academic Employment: Promotions Criteria. University of Oxford.
- UAS 2010. Chapter 11 - The organisation and support of research in Oxford. *Commission of Inquiry Report*. Oxford.
- UAS 2015. Annual Staffing Figures 2014/15 reporting year. University of Oxford.

- UAS. 2016. *Section 2: University structure and administrative organisation* [Online]. University Administration and Services. Available: <http://www.admin.ox.ac.uk/personnel/daproject/damanual/sect2/> [Accessed 01/09/2016].
- VALENTIN, F. & JENSEN, R. L. 2007. Effects on academia-industry collaboration of extending university property rights. *The Journal of Technology Transfer*, 32, 251-276.
- VALENTIN, M. & MARIA, E. 2000. University-industry cooperation: a framework of benefits and obstacles. *Industry and Higher Education*, 14, 165-172.
- VENTOLA, C. L. 2011. Direct-to-consumer pharmaceutical advertising: therapeutic or toxic? *Pharmacy and Therapeutics*, 36, 669.
- VON HIPPEL, E. 1986. Lead users: a source of novel product concepts. *Management science*, 32, 791-805.
- WALDMAN, S. & TERZIC, A. 2010a. Clinical and translational science: from bench-bedside to global village. *Clinical and Translational Science*, 3, 254-257.
- WALDMAN, S. A. & TERZIC, A. 2010b. Clinical and translational science: from bench-bedside to global village. *Clin Transl Sci*, 3, 254-7.
- WALLIMAN, N. 2006. *Social Research Methods*, SAGE Publications.
- WATKINS, C., MOORE, L., HARVEY, I., CARTHY, P., ROBINSON, E. & BRAWN, R. 2003. Characteristics of general practitioners who frequently see drug industry representatives: national cross sectional study. *BMJ*, 326, 1178.
- WILCOX, A. & HIRSCHFIELD, A. 2007. A Framework for Deriving Policy Implications from Research. The University of Huddersfield.
- WILSON, T. 2012. A Review of Business - University Collaboration.
- WINER, M. & RAY, K. 1994. *Collaboration Handbook: Creating, Sustaining, and Enjoying the Journey*, ERIC.
- WITTY, A. 2013. Encouraging a British Invention Revolution: Sir Andrew Witty's Review of University and Growth. London.
- WOHLIN, C., AURUM, A., ANGELIS, L., PHILLIPS, L. & DITTRICH, A., Y. 2012. The success factors powering industry-academia collaboration. *IEEE software*.
- WOLFF, J. 2013. Nobody wants their research impact to be graded 'considerable' in the REF . *The Guardian*.
- WONG, P. K. & SINGH, A. 2013. Do co-publications with industry lead to higher levels of university technology commercialization activity? *Scientometrics*, 97, 245-265.
- WOOLF, S. H. 2008. The meaning of translational research and why it matters. *JAMA*, 299, 211-3.
- YOUNG, L. 2013. Growing your Business: A Report on Growing Micro Businesses.
- ZUCKER, L. G. & DARBY, M. R. 2005. Socio-economic impact of nanoscale science: Initial results and nanobank. National Bureau of Economic Research.
- ZUCKER, L. G., DARBY, M. R. & ARMSTRONG, J. 1998. Geographically localized knowledge: spillovers or markets? *Economic Inquiry*, 36, 65-86.

Appendices

i. Confirmation of ethics approval for study

SOCIAL SCIENCES & HUMANITIES
INTER-DIVISIONAL RESEARCH ETHICS COMMITTEE

Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD
Tel: +44(0)1865 616576 Fax: +44(0)1865 280467
ethics@socsci.ox.ac.uk

Co-ordinator of the SSH IDREC
Research Services



12 November 2014

Natasha Davie
Radcliffe Department of Medicine

Dear Natasha,

Research Ethics Approval

Ref No: SSD/CUREC1/14-022

Title: Collaboration with industry in university translational research and how to accelerate it

The above application has been considered on behalf of the Social Sciences and Humanities Inter-divisional Research Ethics Committee (IDREC) in accordance with the procedures laid down by the University for ethical approval of all research involving human participants.

I am pleased to inform you that, on the basis of the information provided to the IDREC, the proposed research has been judged as meeting appropriate ethical standards, and accordingly approval has been granted.

Should there be any subsequent changes to the project, which raise ethical issues not covered in the original application, you should submit details to the IDREC for consideration.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'MSahan'.

Kate Sahan
Coordinator and Secretary SSH IDREC

cc: Dr Richard Barker, Dr Deborah Gill, Dr Pavel Ovseiko, Prof Alastair Buchan

KS/CK

ii. Questionnaire for PIs conducting translational medical research

Collaboration with industry in translational research

You are receiving this survey as a Principal Investigator with a track record of success in attracting research funding from industry. The University of Oxford's Medical Sciences Division (MSD), the Centre for the Advancement of Sustainable Medical Innovation (CASMI), and the NIHR Oxford Biomedical Research Centre (BRC) are asking for your assistance in a review of the role of industry funding and collaboration with industry in academic research.

All questions concern the seven years between 2007/08 - 2013/14, for which complete data on industry funding in all UK universities is available in the public domain. During this period, Oxford was the most successful university in the UK at attracting industry funding in medical sciences, accounting for 14% of Oxford's total research income in medical sciences.

Your responses will be used to devise new strategies regarding industrial collaboration, which could be developed into guidelines for implementation by the BRC. All responses will remain strictly confidential. Responses will be reported in aggregate form only, and individuals will not be identified. The survey takes about 10 minutes to complete.

Before deciding whether to participate, please read the [Participant Information Sheet](#), which opens in a new window. You will need to indicate that you have read this information before you can provide your informed consent to participate in the survey.

***1. I have read and understood the letter from the Head of the Medical Sciences Division dated 10th November 2014. I consent to the use of the information I provide, and understand that data will be aggregated during analysis so that my responses will not be identifiable.**

☐ Yes, I consent

☐ No, I do not consent

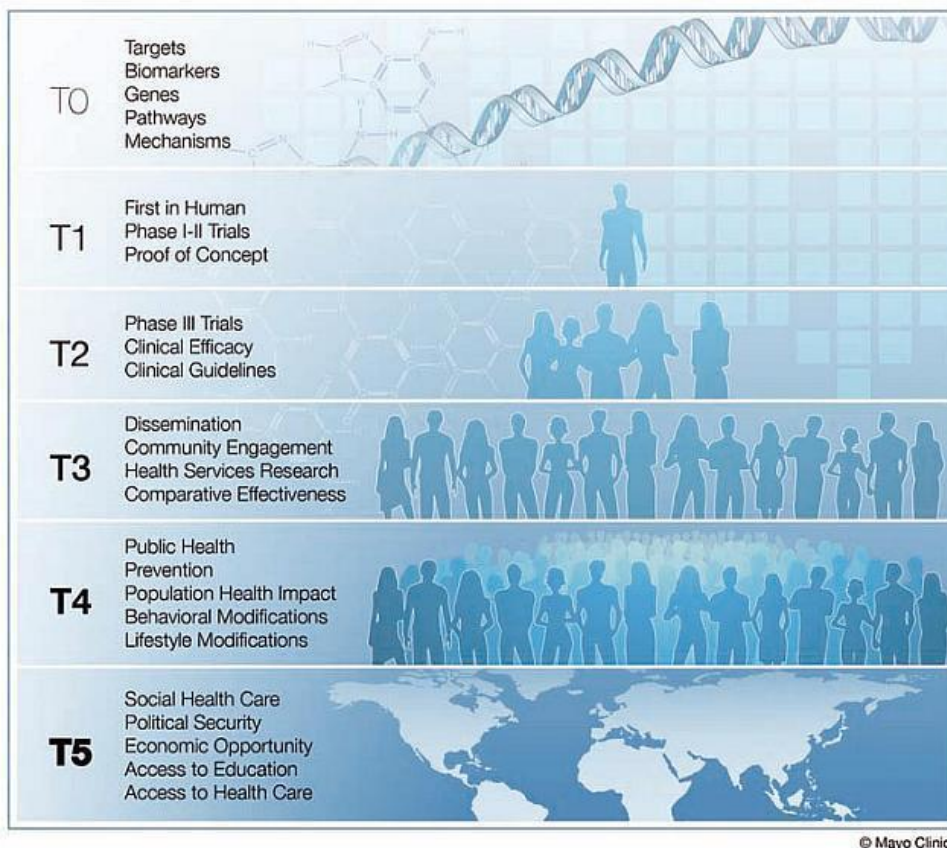
Collaboration with industry in translational research**2. What was your main motivation for entering into collaboration with industry?*****3. Over the last seven years, for what types of collaboration have you received funding from industry?**

Distribute 100 points to reflect the proportion of different purposes (e.g. 50 points = 50% of funding)

Consultations and fee for service, including contract research outsourcing	
Competitive grants sponsored by industry	
Industrial sponsorship of training and education programmes	
Industrial sponsorship of investigator-led research	
Institute–institute liaisons developed on the basis of joint key strategic areas	
Academia, industry and the government partnerships	

Collaboration with industry in translational research

Figure for question 4: The continuum of clinical and translational science (Waldman & Terzic. Clin Transl Sci 2010 3(5): 254-7)



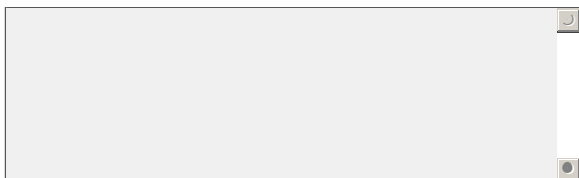
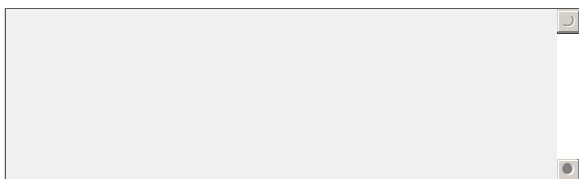
***4. Considering the above figure for reference, how was your funding distributed across the different phases of translational research?**

Distribute 100 points to reflect the distribution (e.g. 50 points = 50% of funding)

T0 (targets, biomarkers, genes, pathways, mechanisms)	
T1 (first in human, phase I-II trials, proof of concept)	
T2 (phase III trials, clinical efficacy, clinical guidelines)	
T3 (dissemination, community engagement, health services research, comparative effectiveness)	
T4 (public health, prevention, population health impact, behavioral modifications, lifestyle modifications)	
T5 (social health care, political security, economic opportunity, access to education, access to health care)	

Collaboration with industry in translational research

In comparison with funding from government and charities, what have been the advantages and disadvantages of industry funding to your research?

5. Advantages:**6. Disadvantages:**

Collaboration with industry in translational research

*7. What have you found to be the major barriers to collaboration with industry in academic translational research?

Please read each of the following statements and indicate the extent to which you agree or disagree.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Basic science orientation of academic research	☐	☐	☐	☐	☐
Divergent areas of research in industry and academia	☐	☐	☐	☐	☐
Short-term orientation of industry research	☐	☐	☐	☐	☐
Long-term orientation of academic research	☐	☐	☐	☐	☐
Slow speed of academic research	☐	☐	☐	☐	☐
High costs of academic research	☐	☐	☐	☐	☐
Ethical issues related to receiving industry funding	☐	☐	☐	☐	☐
Conflicts over intellectual property rights	☐	☐	☐	☐	☐
Industry restrictions on publication and data sharing	☐	☐	☐	☐	☐
Mutual lack of understanding about expectations and working practices	☐	☐	☐	☐	☐
Absence of established university procedures for collaboration	☐	☐	☐	☐	☐
Limited business development and technology transfer support within university	☐	☐	☐	☐	☐
Lengthy contracting process within university	☐	☐	☐	☐	☐
Perceived conflict of interest from university colleagues	☐	☐	☐	☐	☐
Difficulty finding companies with appropriate profile	☐	☐	☐	☐	☐
Inadequate recognition and incentives within university	☐	☐	☐	☐	☐
Lack of government funding to incentivise university-industry collaboration	☐	☐	☐	☐	☐

Other factors or comments

*8. Should the University seek to increase collaboration with industry in translational research?

☐ Yes

☐ No

Please explain your answer. If 'yes', what strategies could the university implement to accelerate collaboration with industry?

Collaboration with industry in translational research**Finally, please tell us about yourself*****9. Which degrees do you hold (select all that apply)?**

- ☐ BMBCh or other medical degree
- ☐ DPhil or other doctoral degree
- ☐ Other degree (not doctoral level)

***10. Do you have a Professorial title?**

- ☐ Yes
- ☐ No

***11. Gender:**

- ☐ Female
- ☐ Male
- ☐ Prefer not to say

***12. Age:**

- ☐ <=30
- ☐ 31-40
- ☐ 41-50
- ☐ 51-60
- ☐ >60

This concludes the survey. To submit your responses press "Done"

Thank you for completing the survey. Your help is greatly appreciated!

MSD, CASMI, and BRC would also be extremely grateful if you could participate in a short interview on the role of industry funding in academic research by Natasha Davie, CASMI Fellow and DPhil candidate in RDM under the supervision of Dr Deborah Gill and Dr Richard Barker.

If you can spare 30 minutes for interview, please submit your email by clicking on this secure link:

<https://www.surveymonkey.com/s/69ZQ5WZ>. The link will open a different electronic form in a new tab to preserve the anonymity of your responses to the survey.

Thank you.

iii. Participant information sheet

**DEAN OF MEDICINE
HEAD OF THE MEDICAL SCIENCES
DIVISION**

Professor Alastair M Buchan DSc LLD (Hon) FMedSci FRCP



University of Oxford, John Radcliffe Hospital, Oxford OX3 9DU
Tel: +44(0)1865 220346 Fax: +44(0)1865 221354
alastair.buchan@medsci.ox.ac.uk <http://www.medsci.ox.ac.uk>

17 November, 2014

Dear Colleague,

Collaboration with industry in translational research and how to accelerate it

I am writing to you in my capacity as Dean of Medicine and Head of the Medical Sciences Division to invite you to participate in a study that explores collaboration with industry in translational research. This study aims to investigate both the role of industry funding in academic translational research and the barriers to such collaboration, as well as to propose strategies to facilitate it. As a Principal Investigator with a track record of success in attracting research funding from industry, your perspective is crucial to this study. Participating may provide benefits such as improved understanding of industrial collaboration, as well as direct input into future university policy on the subject.

This study is being carried out in collaboration with The Centre for the Advancement of Sustainable Medical Innovation (CASMI) (<http://casmi.org.uk>). The survey takes about 10 minutes to complete. Your participation in this study is entirely voluntary and anonymous. If you decide to take part, you are free to withdraw from the study at any time prior to submitting your response and without giving a reason. The information you provide will be aggregated for purposes of analysis so that your responses will not be identified or identifiable. As participation is anonymous, it will not be possible for us to withdraw your data once you have submitted your response. At the end of the survey, you will also be asked if you would like to participate in a short (30 minutes) interview, which will be digitally recorded, transcribed, and anonymised. The aggregated results of the survey and interviews will be analysed and presented internally and used for academic research on university-industry collaboration.

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee. If you have a concern about any aspect of this project, please speak to the relevant researcher (Ms Natasha Davie, NDCLS and CASMI, or Dr Pavel Ovseiko, RDM and MSD, 01865 222049), who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how (s)he intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (Chair, Social Sciences and Humanities Inter-Divisional Research Ethics Committee; Email: ethics@socsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD). The Chair will seek to resolve the matter in a reasonably expeditious manner.

I hope you will decide to participate in the survey, and I look forward to receiving your views.

Yours sincerely,

A handwritten signature in black ink that reads 'Alastair Buchan'.

Alastair M Buchan

iv. Interview topic guide for principal investigators

Interview topic guide for Oxford PIs

Introduction

- Thank participant
- Explain purpose, consent and ability to withdraw
- Request permission for recording.

Questions

1. Please introduce yourself, briefly describing the current role and focus of your research.

Prompt: Diseases/Indications, technologies, basic vs. translational vs. clinical.

2. What roles have industry played in your research?

Prompt: Just funding? Since when? On-going relationships?

3. Have long term relationships with either specific people or companies impacted your collaborations?
4. Have you encountered any barriers to collaboration?
5. From the survey we were able to quantify key barriers to collaboration identified in the literature [**Give participant hand-out 1.**] Looking at the barriers, do you agree with the general order?
6. As a part of the survey several strategies were suggested to improve collaboration [**Give participant hand-out 2.**] Would any of these have been useful to you in your previous interactions, or if they would be useful in the future?

Close

- Thank participant
- Offer transcript/ further information
- Ask if they have any questions

v. Information sheets on barriers and strategies provided to interviewees

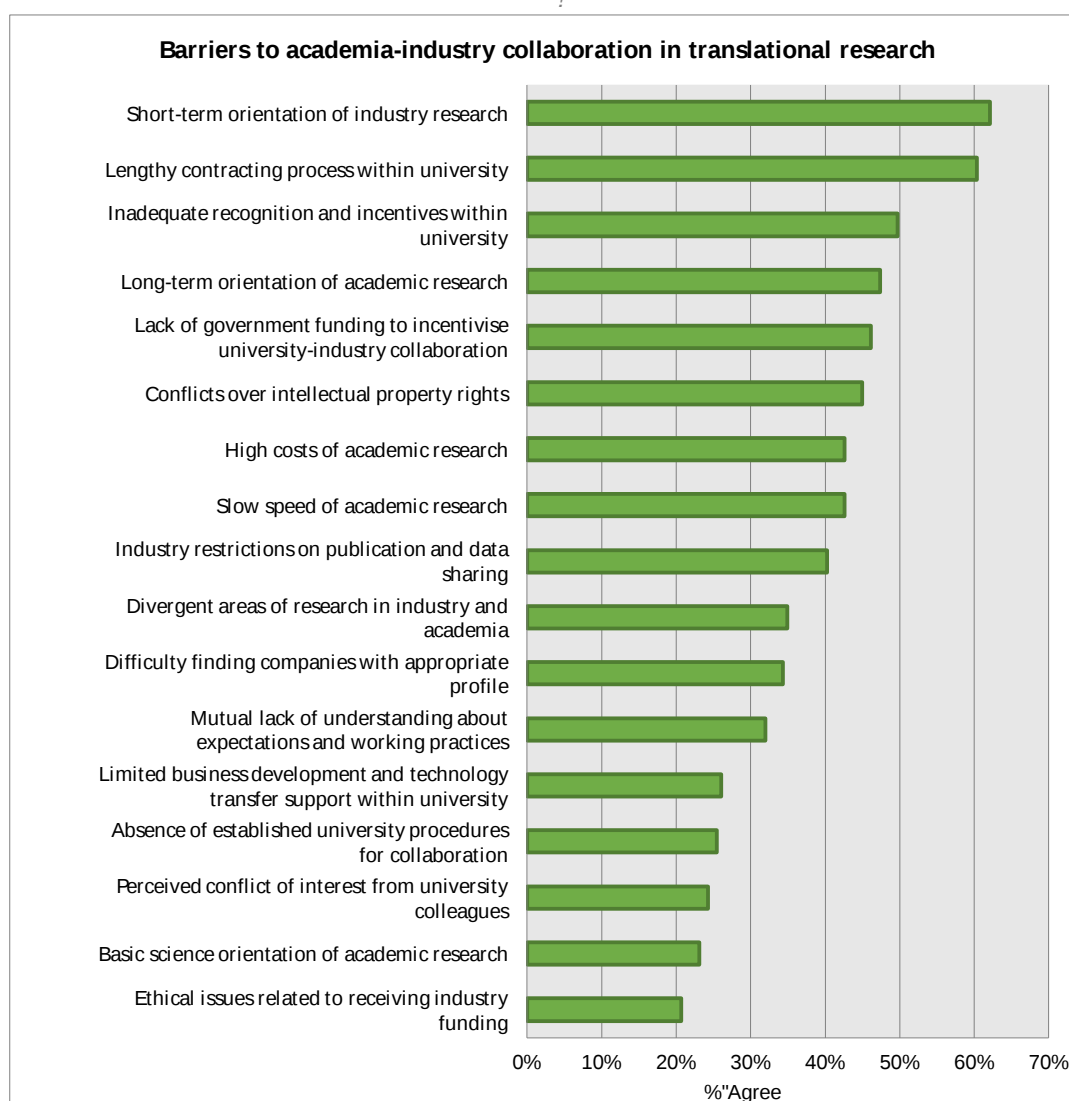
!



Barriers to Collaboration

“What have you found to be the major barriers to collaboration with industry in academic translational research? Please read each of the following statements and indicate the extent to which you agree or disagree.”

!



!



!

Strategies to Improve Collaboration

“What strategies could the university implement to accelerate collaboration with industry?”

!

1. Create a database of all known industrial partners and their interests. AND/ OR creating a database of all academics in Oxford and what they're working on.
2. Form a group or department within the university with the specific purpose of identify, facilitating and maintaining partnerships.
3. Streamline standard contracts to expedite the formation of partnerships (e.g. MTAs, NDAs, IP agreements)
4. Host targeted joint events to 'showcase' academic research and enable networking.
5. Increase exchange of personnel between academia and industry, by creating joint appointments, 'hot-desking', or encouraging sabbaticals.
6. Establish an incentive system within the university that recognises or rewards academics for working with industry. E.g. recognition in grant applications, contribution to department, REF.
7. Use experienced academics to mentor junior researchers, especially where they have experience of collaborating with the same company.
8. Reduce the cost of overheads within the university (either with a government subsidy or by reducing 100% FEC demands)

!

vi. Anonymised List of PIs interviewed

Reference code	Research type*
P01	C
P02	N
P03	N
P04	C
P05	N
P06	C
P07	N
P08	C
P09	N
P10	C
P11	N
P12	N
P13	C
P14	C
P15	N
P16	C
P17	N
P18	C
P19	N
P20	C
P21	C
P22	N
P23	C
P24	C
P25	C
P26	N

*C – Clinical, N- Non-clinical

vii. Interview topic guide for Research Services

Introduction

- Thank participant
- Explain purpose consent and ability to withdraw
- Request permission for recording.

Questions

1. Please tell me about your role within Research Services.

Prompt: Who do you interact with within the university and outside of it? Which processes are you involved with?

2. What is the process of putting in place a contract?

Prompt: Who generally instigates the contracting process? How?

3. How efficient do you think this process is?

Prompt: How? Which areas are most/least efficient.

4. What is the relationship between RS and PIs?

Prompt: How much communication, at what points, perceptions?

5. What interaction does Research Services have with Isis and Business Development?

Other areas: Use of Lambert agreements, use of lawyers, promotional/educational methods

Close

- Thank participant
- Offer transcript/ further information
- Ask for any questions

viii. Interview topic guide for Oxford University Innovation

Introduction

- Thank participant
- Explain purpose consent and ability to withdraw
- Request permission for recording.

Questions

1. Please describe your role within Isis.
2. How does Isis pursue licensees for their patents?

Prompt: At what stage? In advance? How does Isis stay abreast of industry interests?

3. After initial disclosure, how much does Isis interact with academics?
4. What interaction does Isis have with Research Services and Business Development?
5. How important are long term relationships with academics and members of industry?
6. How are links established with industry? How are these links maintained in the face of high turnover of industry personnel?
7. If a licensee for a patent isn't found, how does Isis choose which patents, if any, to maintain internally?
8. In what circumstances would you encourage the formation of a spinout?
9. Is the function and role of Isis promoted within the university?
10. To what extent does Isis need to abide by the restrictions of the university's charitable status?

Close

- Thank participant
- Offer transcript/ further information
- Ask for any questions

ix. Interview topic guide for Business Development

Introduction

- Thank participant
- Explain purpose consent and ability to withdraw
- Request permission for recording.

Questions

1. Please describe your role within BD.
2. What are the main activities you conduct?
3. What are the main issues encountered during these processes?
4. How do BD identify academics or industrial partners?
5. Do BD promote their activities within or outside of the university?

Close

- Thank participant
- Offer transcript/ further information
- Ask for any questions

x. Anonymised List of members of RS, OUI, and BD interviewed

Reference	Group
F1	Business Development
F2	Business Development
F3	Oxford University Innovation
F4	Oxford University Innovation
F5	Oxford University Innovation
F6	Oxford University Innovation
F7	Oxford University Innovation
F8	Oxford University Innovation
F9	RS - Lawyer
F10	Research Services
F11	Research Services
F12	Research Services
F13	Research Services
F14	Research Services
F15	Research Services
F16	Research Services
F17	Research Services