

Spinning Out of Control? How Academic Spinoff Formation Overlooks Medical Device Regulations

Paul Scannell¹, Kathryn Cormican^{1*}

Abstract: This paper investigates the impact of the medical device regulatory framework on the academic spinoff formation process and contributes to knowledge in the domain by expanding and deepening our understanding of its underlying routines and capabilities. A detailed case study focusing on academic spinoff formation in the Irish medical device industry was conducted and found that the consideration given to the medical device regulatory framework significantly lags behind that given to other commercialisation activities. This trend has potential to both significantly delay spinoff formation and negatively impact its potential success and survival. Findings indicate that incorporating expert regulatory knowledge earlier within the process may enhance the spinoff activities within universities, particularly funding, research and capital investment.

Keywords: academic spinoff formation; medical device; regulatory framework; case study

Submitted: Jul 9th, 2019 / Approved: Oct 17th, 2019

Introduction

The commercialisation of scientific and technological knowledge is crucial to economic growth and development (Fontes, 2005; Ndonzuau et al., 2002). Within a knowledge based economy, the university becomes a component of the innovation system where academic technology transfer can occur through several mechanisms such as licensing, publication, cooperative research and development agreements and spinoff formation (Iacobucci and Micozzi, 2014; Rogers et al., 2001). Fontes (2005) describes technology transfer as a process comprising the development of applications for new scientific concepts and turning these into viable technologies, products or services. Rogers et al. (2001) considers technology transfer to be an information transformation process where information is moved from a research and development organisation to a receptor organisation such as a private company. Siegel et al. (2004) investigate the process within an academic setting and defined it in terms of a linear flow model beginning with a discovery by a university scientist through to its patenting and licensing to an existing firm or start-up. However, Rogers et al. (2001) argues that such a linear model of the process may not fully account for external environmental factors such as market demands and regulatory factors.

Spinoffs are identified as a particularly effective means of technology transfer (Rasmussen and Borch, 2010). Researchers have found that they are an important mechanism for the commercialization of research results (Rasmussen and Borch, 2010; Lee, 2001) leading to both job and wealth creation (Rogers et al., 2001; Ndonzuau et al., 2002; Pérez and Sánchez, 2003). Moreover, many researchers have found that spinoffs have a positive effect on the local economy (Iacobucci and Micozzi, 2014; Vincett, 2010; Pérez and Sánchez, 2003). Wennberg et al. (2001) define two discrete spinoff routes: spinoff firms that emerge directly from universities, university spinoffs (USOs), and firms that are spun out by university-educated founders

who pursue careers in private industry and subsequently spinoff from this commercial setting, corporate spinoffs (CSOs). It should be noted, however, that whilst an effective means of technology transfer spin-off creation is also “the most complex way of commercializing academic research” (Iacobucci and Micozzi, 2014). Compared with other technology transfer mechanisms, it is risky and fraught with challenges. Furthermore, there is no guarantee of success. Indeed, research suggests that spinoff ventures emerging from incumbent firms within a specific industry are more likely to commercialise a product than other entrants, such as those emerging from academia (Curran et al., 2011; Wennberg et al., 2001). This is largely attributed to the fact that ventures emerging from incumbent firms inherit sector specific knowledge, something which ventures emerging from academic backgrounds largely lack.

While there are many factors that impede technology transfer and market entry (Pérez and Sánchez, 2003; Van Dierdonck and Debakere, 1988), D’este et al. (2012) highlights the importance of non-financial factors such as market focus, knowledge management and regulation. Indeed, these factors may be more pertinent to specific technologies or industries. For example, regulatory knowledge has been identified as a key knowledge deficit for academics entering the medical device industry (Curran et al., 2011; Chatterji, 2009; van Egeraat et al., 2009; Regnstrom et al., 2010). Academic research must cross the regulatory ‘chasm’ whilst navigating a multitude of regulatory routes and permutations. This market entry barrier may, potentially, be a causative factor for the low incidence and success of spinoff formation.

To investigate this further, this study sought to analyse the academic medical device spinoff formation process through a regulatory lens. We advocate that in order to understand what drives behaviours in specific contexts, distinctive factors (such as processes and practices) pertaining to pertinent issues (such as regulation activities) must

1) College of Engineering & Informatics, National University of Ireland, Galway, University Road, Galway, Ireland

*Corresponding author: kathryn.cormican@nuigalway.ie



be explored and analysed in more detail. While this perspective has emerged in many areas in management research, the underlying microfoundations of these concepts have not received adequate attention in the literature (see Argote and Ren, 2012; Abell et al., 2008; Felin and Foss, 2005) and authors such as Felin et al (2012) are calling for more studies in this space. Accordingly, in an attempt to address this deficit, this study adopts a microfoundations lens to capture empirical data in a specific real-world context.

Three groups namely; academic researchers; facilitators of the spinoff process (such as funding agencies, technology transfer offices and investors); and existing spin off companies, working in the medical device industry in Ireland are examined. Our research explores the perceived level of importance of medical device regulations as well as the level of regulatory knowledge in the sample. We then investigate the spin off formation process in more detail and ascertain when regulatory issues are first considered. We asked participants in our study to rate the criticality of activities that support spin off formation; to determine the barriers to spin off formation and to determine the key factors that influence spin off success and survival. Findings from this analysis are reported and discussed.

The remainder of the paper proceeds as follows. We begin with a synthesis of the extant literature in the area of academic spinoffs to understand the concepts, issues and themes. Next, we provide a summary of the research methods employed in this study. Thereafter we present the findings of our study and discuss these findings relative to the pertinent literature.

Understanding university spinoffs

The knowledge spillover theory of entrepreneurship emphasises the importance of university spinoffs as a mechanism for exploiting knowledge and scientific discoveries created by academic researchers (Carree et al 2014; Audretsch and Lehmann, 2005). According to Uctu and Jafta (2012) there is no universally accepted definition of university spinouts in the literature. They are sometimes referred to as academic spin-offs (Ndonzuau et al., 2002), and spin-outs (Smilor et al., 1990). Link and Scott (2005) contend that university spinoffs are “extraordinarily heterogeneous” and so it is difficult to generalise the research findings. However, there is general consensus regarding two key elements, namely the status of the founder and the nature of the knowledge transferred. Simply put, the founder of an academic spin-off is or was affiliated to a university and the knowledge or invention was originally developed within a university (O’Shea et al., 2008; Link and Scott, 2005; Nicolaou and Birley 2003a; Smilor et al., 1990).

Pérez and Sánchez, 2003 assert that spinoffs transfer technology in two ways; (a) they transfer the technology from the parent organization to the new business entity and (b) they transfer the technology to the market. In an attempt to better understand the types of spinoffs Wright et al., (2006) have classified them along three dimensions the ‘Venture Capital backed’ type, the ‘prospector’ type and the ‘lifestyle’ type.

A detailed synthesis of the literature reveals that much work has been conducted in the space. The extant literature comprises studies from many different thematic areas ranging from motivation and personality characteristics of the founder and the team, to the spinoff process and the role of support organisations. Table 1 presents an overview of the type of academic studies that have been conducted in the area of University spinoff formation.

Table 1. Synthesis of relevant studies

Research theme	Reference
Academic motivation to spinoff	Fini et al., 2008; Henrekson and Rosenberg, 2001; D’Este and Perkmann, 2010; Louis et al., 2001
Characteristics of the spinoff founder	Rosa and Dawson, 2006; Grandi and Grimaldi, 2005; Klofsten and Jones-Evans, 2000
Characteristics of the spinoff team	Knockaert et al., 2011; Vanaelst et al., 2006; Heirman and Clarysse, 2007; Clarysse and Moray, 2004; Grandi and Grimaldi, 2003
Characteristics of the spinoff organisation	Iacobucci et al. 2011; Niosi 2006; Vanaelst et al. 2006; Vohora et al. 2004
The spin off process	Harrison and Leitch, 2010; Poon and Liyanage 2004 Ndonzuau et al 2002; Bower 2003
The role of the parent organisation	Rasmussen and Borch, 2010; Harrison and Leitch, 2010; Lockett and Wright, 2005; Franklin, et al 2001; Bray and Lee, 2000, Rappert and Webster, 1997, Rogers et al., 2001
The role of technology transfer offices	Algieri et al. 2011; Mustar et al 2008; Siegel et al 2007; Lockett et al. 2005; Sharif and Baark, 2008
Role of partners and advisors	Walter et al, 2006; Mosey and Wright, 2007; Hoang and Antoncic, 2003; Perez and Sánchez 2003; Nicolaou and Birley, 2003a,b; Phan et al. 2005; Siegel et al., 2003d

While these studies have contributed significantly to advance our understanding of the concept of the academic spinoff there is a dearth of focused empirical data on specific real-world contexts. More specifically, explicit underlying factors that are essential to the spinoff process in particular industries require further attention. For example, regulatory factors have been found to have a significant influence on the performance of the medical device industry. Blind (2012) argues that regulations increase the hurdles and consequently the compliance costs, which companies must overcome to enter a specific market. Moreover Curran et al. (2011) identified knowledge about regulatory procedures as a critical competency required in the early stages of a university spinoff. Despite this, little progress has been made to advance our knowledge in this domain, Few, if any, studies have specifically looked at the impact of medical device regulatory requirements on the academic spinoff process. This study attempts to bridge this gap.

Research Methodology

Case study analysis was used to determine the relationship between regulatory knowledge and the academic spinoff formation process. The reasons for this are as follows;

- The research undertaken in this study is considered exploratory in nature, as relevant variables have yet to be defined.
- The exact subject under investigation is not very well documented in the literature; therefore, the research could not be conducted experimentally.
- The study investigates complex issues and processes and hence the researcher anticipated that as the research proceeded the issues were likely to unfold to reveal new dimensions.
- A substantial amount of research was concerned with collecting and assessing the views and opinions of participants.

Care was taken to ensure rigour and objectivity in the study. Evidence was collected from multiple sources and triangulated. A purposive, non-probability stratified sample was identified. A non-probability sample is effective when, as in this study, the research is exploring what is occurring. Sample selection was dictated by analytical (rather than statistical) generalisation and replication in accordance with best practice. Samples were carefully selected so that they matched the purpose of the study i.e. structural representation (Voss et al., 2002; Yin, 2014). In total 91 organisations were initially contacted. The sample comprised three cohorts. Group I contained academic researchers, Group II included facilitators of the spinoff process and Group III was made up of founders of medical device spinoff companies (see table 2). Each potential participant was sent a personalised pre-notification invitation outlining the supporting background information, purpose and use of the study as recommended by Fan and Yan, 2010 and Sanchez-Fernandez et al., 2012.

Structured templates were used to help organise and capture the data (Kvale and Brinkmann, 2009). The data collection instrument was pilot tested prior to distribution (Panacek, 2008) and modified to ensure that the correct information was gathered. Data was coded and analysed following best practice protocols. Themes were advanced, and propositions were compared to the extant literature. This helped to strengthen internal validity and reliability.

Table 2. Sample size metrics

Group	Invited	Questionnaire sent (n)	Questionnaire received (n)	Response (%)
Group I	20	13	12	92.3
Group II	62	34	15	44.1
Group III	9	8	7	87.5
Total	91	55	34	61.8

Findings

Overall, 34 responses were received out of a total sample size of 55 resulting in a relatively high response rate of 61.8% (Sauermaann and Roach, 2012). Group I achieved the highest overall response rate of 92.3%, closely followed by Group III at 87.5%. Group II resulted in the lowest response rate of 44.1%. Group I predominately consisted of principal investigators, postdoctoral and postgraduate academics. Most respondents in Group II comprised technology transfer office staff. Other participants included research funding agencies and venture capital firms. In relation to Group III, all respondents were derived from spin-off medical device organisations. Of the 7 respondents, 4 were previously employed in academia and 3 in a medical device firm prior to the spinoff formation. A 100% retention rate was achieved for survey Groups I and III with 85% achieved for Group III. As a result, an overall retention rate of 93% was achieved.

Regulatory knowledge and awareness

Less than half of all respondents deemed medical device regulations to be critical while many considered them to be very important. Respondents in Group I stated that the principle reason for attributing a high level of importance to regulatory requirements was to enable academic research to be taken seriously within the medical device industry. Similarly, respondents from Group II considered due diligence, in terms of regulatory requirements and strategies, as key factors. Respondents from Group III also noted that regulatory strategies and intellectual property protection were critical for securing investment.

The majority (75%) of Group I rated their regulatory knowledge as between fair and good with less than half indicating that they have had prior experience in medical device regulations. However, only 2 respondents considered their knowledge to be very good. 60% of Group III rated their regulatory knowledge as poor at the time of spinoff formation. No one, from either group, considered their level of regulatory knowledge to be excellent.

Interestingly the majority of respondents from Group III initially outsourced regulatory affairs when spinning off their respective organisations. As the organisations have matured, only 1 spinoff remains fully reliant on outsourced regulatory expertise. The remainder have either fully developed in-house regulatory expertise or take a blended approach using both in-house and third party expertise. The latter case appears to be particularly relevant when entering markets with differing regulatory frameworks.

Regulatory considerations in the spin off process

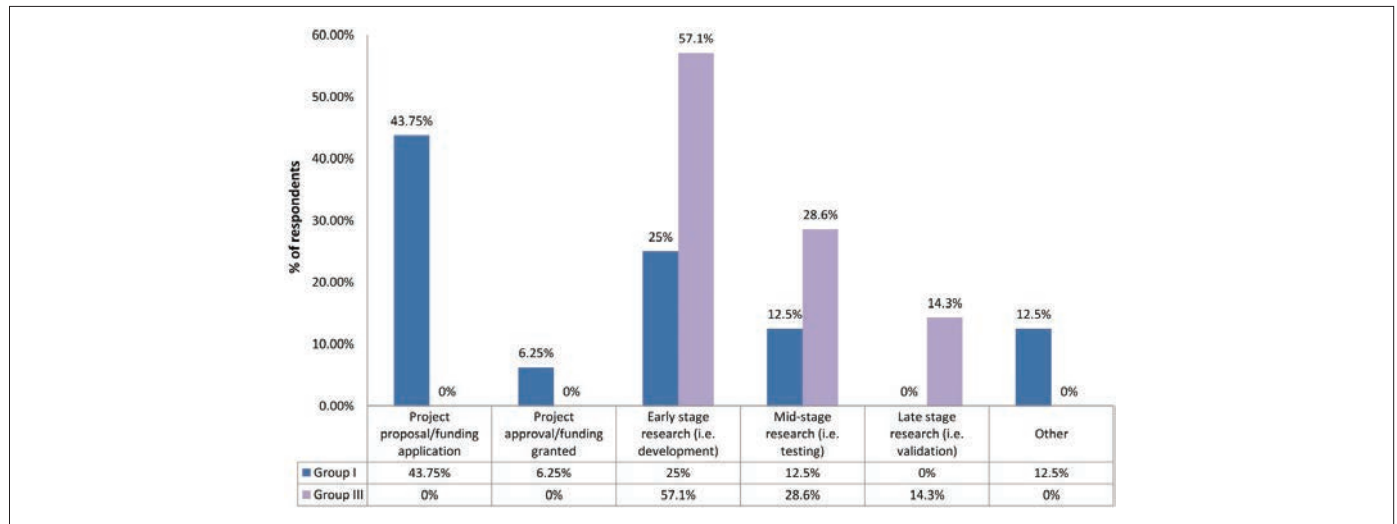
Respondents were asked when they incorporate regulatory requirements and strategies in academic research. 62.5% of respondents in Group I incorporate regulatory requirements and strategies as part of their research proposals and grant applications with 68.8% continuing their incorporation when undertaking pre-clinical research activities. These requirements and strategies are predominantly identified by the researchers themselves with approximately 70% of

researchers attesting to doing so. Those who do not take regulatory considerations into account indicate that the reasoning for this relates to the type of research being conducted, i.e. Proof-of-Principle (PoP) or Proof-of-Concept (PoC) studies and blue sky research.

82.4% of respondents in Group II review regulatory strategies as part of their assessments with 76% considering them to be either very important or critical. All 7 respondents within Group III incorporated regulatory strategies within their business plans.

Actors in Groups I and III were asked to identify at what stage in the process is (Group I), or was (Group III), commercialisation of their research first considered. Three quarters of actors in Group I state that commercialisation is first considered in the early stages of the process between project proposal and early stage research, with the majority considering it at the project proposal stage. This trend is not, however, mirrored by actors in Group III, with 100% indicating early to late stage research as when commercialisation was first considered, with the majority (57.1%) indicating early stage research as the relevant stage.

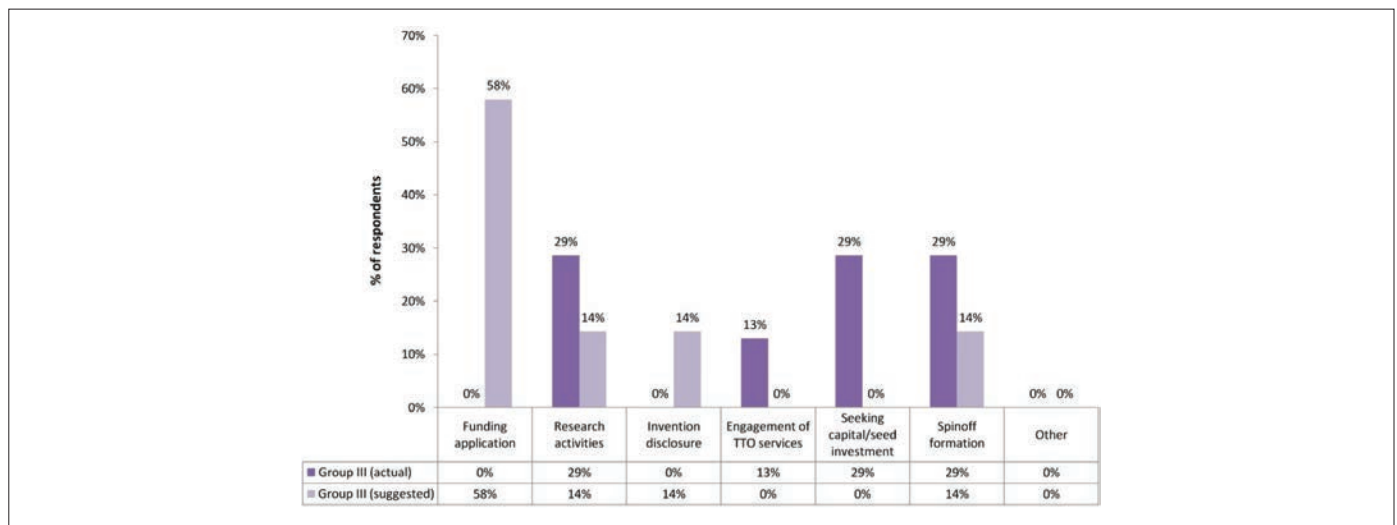
Figure 1. Stage at which commercialisation of academic research is first considered



Participants across all three actor groups were asked to indicate at what stage regulatory considerations should begin to be considered when academic research is being undertaken. Over half of respondents in Groups II and III believe they should be considered in the first stage, funding application, whilst only 25% of Group I have the same opinion. There is, however, an overall trend indicating that regulatory requirements require consideration in the earlier rather than later stages of the process.

The actors within Group III were investigated further to ascertain whether the process stage at which they indicated regulations should be first considered matched that at which they were in practice. Whilst 58% of these respondents consider the funding application stage to be the most relevant one at which regulatory requirements should be considered, none however implemented this in practice. 58% of respondents indicated that regulatory requirements were first considered in the latter stages of the process; those of seeking investment and spinoff formation.

Figure 2. Actual versus suggested stage at which regulatory requirements are considered during the spinoff formation process



Supports to spin off formation

All three actor groups were asked to rate the criticality of the activities which support spinoff formation e.g. funding, due diligence, commercial assessment, technical assessment and regulatory assessment. Respectively, 62.5% and 68.75% of respondents within Group I deemed funding and due diligence to be critical in supporting spinoff formation. Commercial, technical and regulatory assessments were largely regarded as having the same level of criticality.

Within Group II, funding, due diligence and commercial and technical assessments were broadly considered as having equal weight. Overall, commercial assessment was considered as most important with 82.4% of respondents deeming it to be critical. Regulatory assessment was considered as being critical by just 47.1% of respondents in this group.

Funding was considered the most important factor in supporting spinoff formation by respondents in Group III with 85.7% viewing

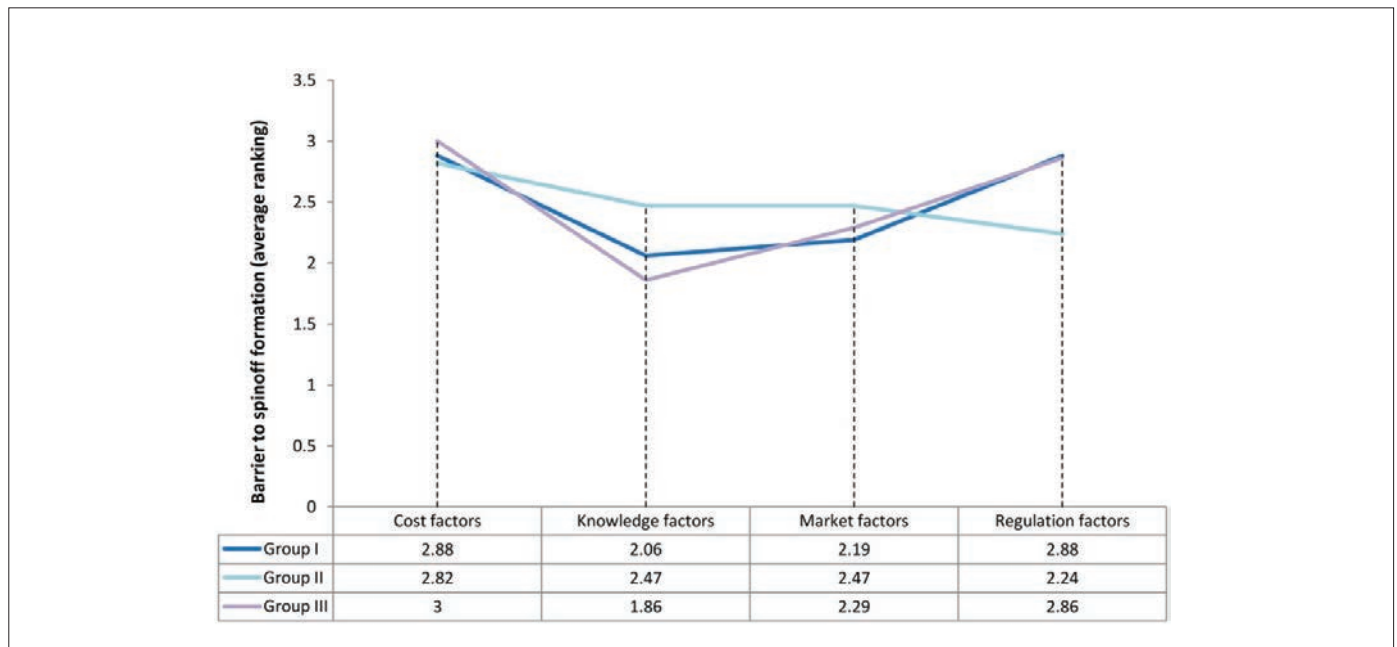
it as being critical. The levels of importance attributed to due diligence, and technical and regulatory assessments were equally distributed at 57.1% critical, 28.6% very important and 14.3% important.

Participants were asked to rank four categories of barriers to spinoff formation namely

1. Cost factors (i.e. financing)
2. Knowledge factors (i.e. Acquiring the appropriate staff)
3. Market factors, (i.e. Competition and customer demand)
4. Regulatory factors (i.e. Meeting requirements).

Four weighted ranking levels were provided: low (1), medium (2), high (3) and highest (4). The average ranking for each barrier is presented in Figure 3.

Figure 3. Average ranking of barriers to spinoff formation



Across all three groups cost factors were considered as being the highest barrier to spinoff formation with average weighted rankings of between 2.82 and 3. Respondents in Group III attributed the highest average weighted ranking (3) to this factor. Regulatory factors were considered as being second to cost factors by Groups I and III followed by knowledge and market factors which were broadly attributed the same average weighted ranking. The opposite trend was observed in responses received from Group II; knowledge and market factors were equally placed second at 2.47 followed by regulatory factors with a value of 2.24.

To investigate what influences a spinoff's success and survival all three groups were asked to rate the relative importance of five

factors: funding, intellectual property (IP) protection, market analysis, research and development, and regulatory strategy. All three groups considered continued funding to be the most critical factor to ensure success and survival. Equally, both IP protection and regulatory strategy were considered second to continued funding by actors in Group I with 32.5% of respondents considering such factors to be critical. At 42.9%, a similar trend is seen in Group III with the addition of market analysis and awareness. Group II, however, places more importance on market awareness with 58.8% considering it to be critical. Continued research and development is considered critical by only 18.75%, 17.6% and 14.3% of respondents in Group I, II and III respectively. It is, however, acknowledged as being very important across all three groups.

Influence of early incorporation of regulations

The opinions of actors in Groups II and III were sought on how the early identification of regulatory requirements by researchers and the incorporation of regulatory strategies within academic research could improve the spinoff formation process. There is strong agreement between Groups II (70.6%) and III (71.4%) that incorporating regulatory strategies within funding proposals would enhance both the application process and evaluation process.

There is further strong agreement between the groups with approximately 70% of both groups considering regulatory strategies would enhance business plans when embarking on the spinoff process. Regarding capital investment applications and reviews, and how the incorporation of regulatory strategies could enhance the process, the opinions of both groups mirror each other. However, in both cases there is not as strong an agreement as previously seen, with approximately 55% strongly agreeing and 42% agreeing.

There is diverging opinion as to whether the early identification of regulatory requirements and strategies would reduce spinoff costs and time to market. 71.4% of respondents in Group III strongly believe cost and time to market could be reduced but only 35.3% of Group II has the same opinion. 5.9% of Group II disagree, primarily as they believe that by identifying such requirements both cost and time may be increased to enable such requirements to be met. This, however, is countered by the agreement of those who agree; whilst initially both costs and time may increase it acts to reduce errors which, if realised at a later stage, could significantly increase both costs and time, particularly in the case of innovative technologies.

Discussion

Regulatory knowledge and awareness

Results reveal that 87% of respondents from Groups I and III rate the importance of medical device regulations as being either very important or critical, particularly in the case of applied research. This is reflected in the finding that over 60% of Group I incorporate regulations within both funding applications (25%) and pre-clinical research activities (38%) whilst all responses received from Group III indicated that regulatory requirements were incorporated within their business plans. However, 65% of these respondents rated their regulatory knowledge as between poor and fair. Furthermore, 82% of those who review research for the purposes of funding, patenting or investment (i.e. Group II) also review the associated regulatory strategies with 76% considering them to be a very important or critical component of the research.

There is an apparent inequality between regulatory awareness, or perceived importance, and knowledge. This inference is supported by those who found that spinoffs who inherit non-technical complementary knowledge, such as regulatory knowledge, are more likely to successfully commercialise a medical device and that a lack of such knowledge may be an important contributory factor to low incidence of spinoff formations (Curran et al., 2011, Chatterji, 2009 and van

Egeraat et al. 2009). It has been previously identified that spinoffs who emerge from corporate parents are more liable to inherit this knowledge than academic spinoffs (Wennberg et al., 2001); this is also reflected in the findings of the survey which reveal that, whilst approximately half of the actors in Group I indicate having prior regulatory experience; the majority has been gained through academic pursuits such as workshops etc. Of the 7 responses received from academic spinoffs, over 70% relied on outsourced regulatory expertise.

Regulatory considerations in the spin off process

A disparity between the stage at which commercialisation of research and the stage at which regulatory requirements are first considered is evident where just under half of Group I respondents stated that commercialisation decisions are made at the project proposal or funding application stage. Comparatively, only 25% considered that regulatory requirements should be considered at the same stage. This gap is further exacerbated when the responses of Group III are reviewed. Whilst commercialisation decisions were made at a later stage to that indicated by Group I, regulatory considerations were also considered at a much later stages of the spinoff process; 58% of respondents indicated that they were only considered when seeking investment or at the time of actual spinoff. This finding mirrors that found by the European Medicines Agency's SME Office who found that SMEs also tend to seek their advice at the later stages of the development process.

This observation appears to contradict the finding that over 60% of Group I incorporate regulations within both funding applications and pre-clinical research activities. The reason for this contradiction is not immediately evident. Perhaps, the level of initial regulatory consideration is minimal with the burden of regulatory compliance only becoming evident at later stages. Interestingly, 58% of actors in Group III would now first consider the identification of regulatory requirements at the earliest stage.

Responses from Group II also indicated that regulations should be considered sooner rather than later with 53% indicating funding application as the most appropriate stage. A strong case can be made for the earlier consideration of regulations for applied research, whereas the commercial viability of, and hence the need to consider regulatory requirements for, exploratory research may only become apparent at a later stage. What we may deduce from these findings is that, although regulations are considered they may only be accurately considered during the later stages of the commercialisation process.

A theoretical explanation of this, based on skill complementarities which are required for entrepreneurs, is proposed by Lazear (2004). This theory recognises that entrepreneurs must have knowledge of a wide variety of business areas and skill complementarities. Empirical evidence suggests academics with a balanced skill profile experienced shorter time-lags in spinoff formation than academics with an unbalanced skill profile. An unbalanced skill profile may be considered as a barrier to spinoff formation, more specifically, a revealed barrier which is defined as barriers which emerge due to the direct

experience in the engagement of innovation activities resulting in the awareness of the associated difficulties (D'Este et al., 2012). Regulatory knowledge may be considered as a revealed barrier with potential to delay spinoff formation; this is perhaps reflected in the shift in the opinions of Group III respondents as to when regulatory factors should first be considered.

In order to overcome these barriers Muller (2010) suggests that matching spinoff founders with complementary skill profiles should be taken into account when designing policy measures to foster spinoff creation such as supporting and assisting founders.

Supports to spin off formation

As expected, funding is largely considered as the most critical aspect across all three survey groups for both enabling spinoff formation and supporting its success and survival. However, regulatory assessment is ranked as one of the least critical factors in supporting spinoff formation. It could be argued that this is due to the formation of a spinoff company not being dependent on complying with medical device regulations. It is this market activity which is ultimately critical to the success and survival of the company, an argument supported, to a certain degree, by the relative increase in the percentage of respondents who rank regulatory assessment as being critical in supporting success and survival; regulatory assessment moves from being one of the least critical factors for spinoff formation to being rated on par with intellectual property/due diligence factors in terms of success and survival by actors in Groups I and III. Safeguarding and marketing the universities intellectual property is the technology transfer office's primary motive whilst commercialising university-based research for financial return is that of investors (Siegel et al., 2004).

Regulatory requirements have a direct relationship with funding requirements, in terms of both initial and continued funding but differ across the different medical device classifications which, in turn, heavily influences the costs associated with ensuring compliance. The weighting attributed to criticality of regulatory factors is perhaps undervalued, and in particular that attributed during spinoff formation. Perhaps if there were more awareness of the regulatory requirements and their implications at an earlier stage, the criticality attributed to them in supporting both the spinoff venture formation and the subsequent success and survival may be higher?

Influence of early incorporation of regulations

Although regulatory requirements are often intended to be first considered during the early stages of academic research, they are more likely to only be appropriately considered during later stages. Over 70% of respondents from both groups I and II strongly agree that the early incorporation of regulatory strategies within funding applications would enhance the funding process. However, whilst funding agencies are conscious of the regulatory needs it only becomes a critical factor in the case of applied research. The funding required to conduct such applied research can be heavily influenced by the specific regulatory requirements of the medical device, particularly those of

the required pre-clinical and animal testing and potential necessity to conduct clinical investigations. Incorporating these requirements at this stage not only gives a better estimate of the required funding and anticipated research duration but also allows for both pre-clinical and clinical work to be conducted within the requirements of the legislation. This latter point has been demonstrated by the Investigational Assistance Program (IAP) at the University of Minnesota's Academic Health Center (AHC) (Arbit and Paller, 2006). Prior to the establishment of the program 24 pre-existing clinical studies were being conducted; only 5 were shown to meet the required regulatory obligations. Subsequent to the establishment of the IAP, 20 new clinical studies commenced bringing the total number of active studies to 44; all of which were shown to be compliant with the regulations and, in some cases, the amount of research time saved amounted to one year.

The early incorporation of regulatory strategies within a business plan would enhance the spinoff process. Muller (2010) observes having complementary skills reduces the time-lag in the establishment of an academic spinoff firm supported by Grimaldi et al. (2011) who notes that one of the primary challenges in the evolution of technology transfer is that of identifying suitable actors to bridge the academic and commercial divide. In the medical device industry, this particularly concerns regulatory requirements which rapidly increase as a medical device approaches market entry. The suggestion of the earlier incorporation of regulatory strategies to support spinoff formation is further supported by Curran et al. (2011) who note that it may be prudent to include people with strong industry knowledge (i.e. regulatory knowledge) in the management team of university spin-offs at the earliest possible stage.

Venture capitalists prefer to invest after the seed stage once ventures have become established and are likely to have already demonstrated regulatory compliance where regulatory considerations may not be a significant contributor to investment decisions (Wright et al., 2006). It appears the decision to invest is largely focused on factors which directly contribute to return on investment such as IP protection and market opportunity. In the case of ventures seeking seed or start-up capital the influence of regulatory considerations on investment decisions are liable to increase. The benefits of addressing regulatory requirement at an early stage can be seen to be dependent on the type of capital being sought: seed, start up, early stage, expansion stage or late stage.

Conclusions

Our findings reveal is that there is an apparent degree of separation between the academic spinoff formation process and the regulatory process, with the regulatory process lagging that of the spinoff process. Whilst the medical device regulatory framework may not prevent a spinoff from forming, it certainly has the potential to delay, perhaps significantly, market entry. To temper this, these two processes should be seen to work in parallel from the earliest stage of the commercialisation process. Furthermore, given the nuances of the medical device regulatory framework, expert regulatory input is

highly recommended to be sought at this early stage. Such an approach can be seen to significantly support the spinoff process across several stages:

- **Funding:** both the duration and resources required to commercialise medical device research are heavily influenced by the specific regulatory requirements of the concerned technology. A better commercial case for the medical device, based on more accurate estimates of duration and cost, resulting from a sound understanding of regulatory requirements would be provided for.
- **Research Activities:** conducting pre-clinical testing in line with relevant standards reduces the burden of demonstrating conformance to the relevant medical device legislation. This is a long term benefit which pre-empts the regulatory requirements which increase substantially as market entry approaches.
- **Capital Investment:** market access is dictated by meeting the regulatory requirements. This is particularly pertinent in the case of highly innovative medical technologies seeking seed or start-up capital. Demonstrating an astute regulatory strategy corroborates market access strategies.

A key aspect of this is the establishment of a micro enterprise support structure should be established to support indigenous start-ups at third level. To foster and support spinoff creation within the medical device sector it is essential that this structure incorporates a regulatory support mechanism. Such a support mechanism may become a necessity should the proposed new medical device regulations come into force as currently proposed as there will be a requirement for manufacturers to have available within their organisation a person responsible for regulatory compliance activities who possesses expert knowledge in the field of medical devices. In the case of micro and small enterprises, whilst they are not required to have such expertise within their organisation they will be required to have such person permanently and continuously at their disposal.

Our analysis makes important contributions to technology management research. Our findings provide an insight into the impact of medical device regulations on academic spinoff formation across a wide and diverse range of stakeholders. Prior research recognizes that regulations are essential to commercialisation success and our findings add to this debate. These results allow us to advance the general theoretical development of the field. These findings are useful in furthering our understanding of how to best bridge the gap between theory and practice. Hence, this study is of managerial relevance to entrepreneurs. Certain limitations of this study should be noted. This study focused solely on academic spinoffs operating in the medical technology industry in a small open economy i.e. Ireland. Consequently, the context of this study is quite specific, and the explanatory power of our findings may be limited to this particular industry or country. Future studies could strive to address this deficit.

References

- Abell, P., Felin, T. & Foss, N. (2008). Building micro-foundations for the routines, capabilities, and performance links. *Managerial and Decision Economics*, 29, 489–502.
- Arbit, H. & Paller, M.S. (2006). A program to provide regulatory support for investigator-initiated clinical research. *Academic Medicine*, 81, 146-15
- Algieri, B., Aquino, A. & Succurro, M. (2011). Technology transfer offices and academic spin-off creation: the case of Italy. *The Journal of Technology Transfer*, 38(4), pp.382–400.
- Argote, L. & Ren, Y. (2012). Transactive memory systems: a micro foundation of dynamic capabilities. *Journal of Management Studies*, 49(8), pp.1375–1382.
- Audretsch, D.B. & Lehmann, E.E. (2005). Mansfield's Missing Link: The Impact of Knowledge Spillovers on Firm Growth. *Essays in Honor of Edwin Mansfield*, 271–274.
- Blind, K. (2012). The influence of regulations on innovation: A quantitative assessment for OECD countries. *Research Policy*, 41, 391–400.
- Bower, D. J. (2003). Business model fashion and the academic spinout firm. *R&D Management*, 33(2), 97-106.
- Bray, M.J. & Lee, J.N. (2000). University revenues from technology transfer. *Journal of Business Venturing*, 15(5-6), 385–392.
- Carree, M., Malva, A. D., & Santarelli, E. (2014). The contribution of universities to growth: Empirical evidence for Italy. *The Journal of Technology Transfer*, 39(3), 393–414.
- Chatterji, A. K. (2009). Spawned with a silver spoon? Entrepreneurial performance and innovation in the medical device industry. *Strategic Management Journal*, 30, 189–206.
- Clarysse, B., & Moray, N. (2004). A process study of entrepreneurial team formation: The case of a research-based spin-off. *Journal of Business Venturing*, 19(1), 55–79.
- Curran, D., van Egeraat, C., & O'Gorman, C. (2011). New entrants and inherited competence: The evolution of the Irish biotech sector. Working Paper No.66, National Institute for Regional and Spatial Analysis.
- D'este, P., Iammarino, S., Savona, M., & von Tunzelmann, N. (2012). What hampers innovation? Revealed barriers versus deterring barriers. *Research Policy*, 21, 482–488.
- D'Este, P., & Perkmann, M. (2010). Why do academics engage with industry? The entrepreneurial university and individual motivations. *The Journal of Technology Transfer*, 36(3), 316–339.
- Fan, W. & Yan, Z. (2010). Factors affecting response rates of the web survey: A systematic review. *Computers in Human Behaviour*, 26, 132–139.

- Felin, T. & Foss, N. J. (2005). Strategic organization: a field in search of micro-foundations. *Strategic Organization*, 3, 441–55.
- Felin, T., Foss, N. J., Heimeriks, K. H. & Madsen, T. L. (2012). Micro-foundations of Routines and Capabilities: Individuals, Processes, and Structure. *Journal of Management Studies*, 49: 1351–1374.
- Fontes, M. (2005). The process of transformation of scientific and technological knowledge into economic value conducted by biotechnology spin-offs. *Technovation*, 25, 239–347.
- Franklin, S. J., Wright, M., & Lockett, A. (2001). Academic and surrogate entrepreneurs in university spin-out companies. *The Journal of Technology Transfer*, 26(1-2), 127–141.
- Grandi, A., & Grimaldi, R. (2003). Exploring the networking characteristics of new venture founding teams. *Small Business Economics*, 21(4), 329–341.
- Grandi, A., & Grimaldi, R. (2005). Academics' organizational characteristics and the generation of successful business ideas. *Journal of Business Venturing*, 20(6), 821–845.
- Harrison & Leitch, 2010; Harrison, R. T., & Leitch, C. (2010). Voodoo Institution or Entrepreneurial University? Spin-off companies, the entrepreneurial system and regional development in the UK. *Regional Studies*, 44(November), 1241–1262.
- Heirman, A., & Clarysse, B. (2007). Do intangible assets and pre-founding R&D matter for innovation speed in start-ups. *Journal of Product Innovation Management*, (4), pp.303–315.
- Henrekson, M., & Rosenberg, N. (2001). Designing efficient institutions for science-based entrepreneurship: Lesson from the US and Sweden. *The Journal of Technology Transfer*, 26(3), 207–231.
- Hoang, H. & Antoncic, B. (2003). Network-based research in entrepreneurship. *Journal of Business Venturing*, 18(2), pp.165–187.
- Iacobucci, D., Iacopini, A., Micozzi, A., & Orsini, S. (2011). Fostering entrepreneurship in academic spin-offs. *International Journal of Entrepreneurship and Small Business*, 12(4), 513–533.
- Iacobucci, D., & Micozzi, A. (2014). How to evaluate the impact of academic spin-offs on local development: an empirical analysis of the Italian case. *The Journal of Technology Transfer*, 1–19.
- Klofsten, M., & Jones-Evans, D. (2000). Comparing Academic Entrepreneurship in Europe – The Case of Sweden and Ireland, *Small Business Economics*, 14(4), 299–309.
- Knockaert, M., Ucbasaran, D., Wright, M., & Clarysse, B. (2011). The relationship between knowledge transfer, top management team composition, and performance: The case of science-based entrepreneurial firms. *Entrepreneurship: Theory and Practice*, 35(4), 777–803.
- Kvale, S. & Brinkmann, S. (2009). *Interviews: Learning the Craft of Qualitative Research Interviewing* (2nd Edition). Thousand Oaks, CA: Sage, 2009.
- Lazear, E.P. (2004). Balanced Skills and Entrepreneurship. *American Economic Review*, 94(2), 208–211.
- Link, A. N., & Scott, J. T. (2005). Opening the ivory tower's door: An analysis of the determinants of the formation of US university spin-off companies. *Research Policy*, 34(7), 1106–1112.
- Lockett, A., & Wright, M. (2005). Resources, capabilities, risk capital and the creation of university spin-out companies. *Research Policy*, 34(7), 1043–1057.
- Lockett, A., Siegel, D., Wright, M., & Ensley, M. D. (2005). The creation of spin-off firms at public research institutions: Managerial and policy implications. *Research Policy*, 34(7), 981–993.
- Louis, K. S., L. M. Jones, M. S. Anderson, D. Blumenthal & Campbell, E. G. (2001). Entrepreneurship, secrecy, and productivity: a comparison of clinical and non-clinical life sciences faculty, *Journal of Technology Transfer*, 26(3), 233–245.
- Mosey, S., & Wright, M. (2007). From Human Capital to Social Capital: A Longitudinal Study of Technology-Based Academic Entrepreneurs. *Entrepreneurship Theory & Practice*, 31(6), 909–935.
- Muller, K. (2010). Academic spin-offs transfer speed - analyzing the time from leaving university to venture. *Research Policy*, 39:189–199.
- Mustar, P., Wright, M., & Clarysse, B. (2008). University spin-off firms: lessons from ten years of experience in Europe. *Science and Public Policy*, 35(2), 67–80.
- Ndonzuau, F. N., Pirnay, F., & Surlemont, B. (2002). A stage model of academic spin-off creation. *Technovation*, 22(5), 281–289.
- Nicolaou, N., & Birley, S. (2003). Academic networks in a trichotomous categorisation of university spinouts. *Journal of Business Venturing*, 18(3), 333–359.
- Nicolaou, N., & Birley, S. (2003). Social Networks in Organizational Emergence: The University Spinout Phenomenon, *Management Science*, 49(12), 1702–1725.
- Niosi, J. (2006). Success factors in Canadian academic spin-offs. *The Journal of Technology Transfer*, 31(4), 451–457.
- O'Shea et al. 2008; O'Shea, R. P., Chugh, H., & Allen, T. J. (2008). Determinants and consequences of university spinoff activity: a conceptual framework. *The Journal of Technology Transfer*, 33(6), 653–666.
- Panacek, E. A. (2008). Survey based research: Performing the survey. *Air Medical Journal*, 27(2), 64–66.
- Pérez, M. P., & Sánchez, A. M. (2003). The development of university spin-offs: early dynamics of technology transfer and networking. *Technovation*, 23(10), 823–831.

- Phan, P. H., Siegel, D. S., & Wright, M. (2005). Science parks and incubators: observations, synthesis and future research, *Journal of Business Venturing*, 20(2), 165–182.
- Poon, P. & Liyanage, S. (2004). Commercialisation of biotechnology in newly industrialised economies. *International Journal of Biotechnology*, 6(2/3), 243.
- Rappert, B. & Webster, A. (1997). Regimes of ordering: the commercialization of intellectual property in industrial-academic collaborations. *Technology Analysis & Strategic Management*, 9(2), 115–130.
- Rasmussen, E., & Borch, O. J. (2010). University capabilities in facilitating entrepreneurship: A longitudinal study of spin-off ventures at mid-range universities. *Research Policy*, 39(5), 602–612.
- Regnstrom, J., Koenig, F., Aronsson, B., Reimer, T., Svendsen, K., Tsigkos, S., Flamion, B., Eichler, H. G., & Vamvakas, S. (2010). Factors associated with success of market authorisation applications for pharmaceutical drugs submitted to the European medicines agency. *European Journal of Clinical Pharmacology*, 66(1), 39–48.
- Rogers, E. M., Takegami, S., & Yin, J. (2001). Lessons learned about technology transfer. *Technovation*, 21, 253–261.
- Rosa, P., & Dawson, A. (2006). Gender and the commercialization of university science: academic founders of spinout companies. *Entrepreneurship and Regional Development*, 18(4), 341–366.
- Sanchez-Fernandez, J., Muñoz-Leiva, F., & Montoro-Ríos, F. J. (2012). Improving retention rates and response quality in web-based surveys. *Computers in Human Behaviour*, 28, 507–514.
- Sauermann, H. & Roach, M., 2012. Science PhD Career Preferences: Levels, Changes, and Advisor Encouragement L. A. Nunes Amaral, ed. *PLoS ONE*, 7(5), 36307.
- Sharif, N. & Baark, E. (2008). Mobilizing technology transfer from university to industry, *Journal of Technology Management China*, 3(1), 47–65.
- Siegel, D. S., Veugelers, R., & Wright, M. (2007). Technology transfer offices and commercialization of university intellectual property: performance and policy implications. *Oxford Review of Economic Policy*, 23(4), 640–660.
- 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.
- Siegel, D. S., Westhead, P. & Wright, M. (2003d). Science parks and the performance of new technology-based firms: a review of recent U.K. evidence and an agenda for future research, *Small Business Economics*, 20, 177–184.
- Smilor, R. W., Gibson, D. V., & Dietrich, G. B. (1990). University spin-out companies: Technology start-ups from UT-Austin. *Journal of Business Venturing*, 5(1), 63–76.
- Uctu, R., & Jafta, R. C. (2012). Academic entrepreneurship in South East Asia: an exploratory study of spin-offs in biotechnology from Hong Kong universities. *Asian Journal of Technology Innovation*, 20(1), 141–154.
- Van Dierdonck, R., & Debackere, K. (1988). Academic entrepreneurship at Belgian Universities, *R&D Management*, 18 (4) (1988), pp. 341–354.
- Van Egeraat, C., Curran, D., & Kerr, A. (2009). Social and spatial structures of collaboration and innovation in the knowledge economy. Deliverable 11.2 for EU FP6 OPAALS research project, National Institute for Regional and Spatial Analysis.
- Vanaelst, I., Clarysse, B., Wright, M., Lockett, A., Moray, N., & S'Jegers, R. (2006). Entrepreneurial team development in academic spinouts: An examination of team heterogeneity. *Entrepreneurship Theory and Practice*, 30(2), 249–271.
- Vincett, P. S. (2010). The economic impacts of academic spin-off companies, and their implications for public policy. *Research Policy*, 39(6), 736–747.
- Vohora et al. 2004; Vohora, A., Wright, M., & Lockett, A. (2004). Critical junctures in the development of university high-tech spinout companies. *Research Policy*, 33(1), 147–175.
- Voss, C., Tsikriktsis, N. & Frohlich, M. (2002). Case research in operations management, *International Journal of Operations & Production Management*, 22 (2), 195 - 219
- Walter et al 2006; Walter, A., Auer, M., & Ritter, T. (2006). The impact of network capabilities and entrepreneurial orientation on university spin-off performance. *Journal of Business Venturing*, 21(4), 541–567.
- Wennberg, K., Wiklund, J. & Wright, M. (2001). The effectiveness of university knowledge spillovers: performance differences between university spinoffs and corporate spinoffs, *Research Policy*, 40 (2011), 1128–1143.
- Wright, M., Lockett, A., Clarysse, B., & Binks, M. (2006). University spin-out companies and venture capital. *Research Policy*, 35, 481–501.
- Yin, R.K. (2014). *Case study research: Design and methods (5th ed.)*. Thousand Oaks, CA: Sage publications.

