Success of New Pharmaceutical Product Development – the Effect of Development Partnerships with Contract Research Organisations

Abstract

In recent decades firms have collaborated with external partners for NPD to cope with increasing product complexity and demand. Even though many studies have investigated success and failure in NPD and inter-firm partnerships, products keep failing and NPD projects are abandoned or delayed. Thus this PhD project aims to better explain the success of new products in the late development stage in the pharmaceutical industry by studying the network in which pharmaceutical firms, hospitals and CROs are embedded.

Introduction and proposal

Developing and commercialising successful new products is the key to maintaining a competitive position in the marketplace (Griffin and Page, 1996). One third of sales and profits come from new products (Barczak et al., 2009). In the field of new product development (NPD), a large number of studies have identified factors contributing to the failure or success of new products (Evanschitzky et al., 2012; Montoya-Weiss and Calantone, 1994; Page and Schirr, 2008). The NPD field has been one of the few areas where continued advances in science have supported the actual practice of NPD due to a close relationship between academics and consultants, who translate the best of the models into application (Evanschitzky et al., 2012).

However, firms still struggle with developing new products. Just half of the new commercialised products are successful from a profit perspective (Barczak et al., 2009). New products fail at an alarmingly high rate (Cooper, 1990) and many innovative projects are either abandoned or delayed (Radas and Bozic, 2012). Although NPD success attracts the attention of academics and industry, it remains a multi-dimensional concept difficult to predict and measure (Griffin and Page, 1993). NPD literature lacks original theory (Ernst, 2002; Evanschitzky et al., 2012; Hauschildt and Salomo, 2007) and the importance of traditional success factors is declining over time (Evanschitzky et al., 2012). Thus, the NPD literature might have overlooked or not yet identified some factors that can help explain NPD success (Cooper and Kleinschmidt, 2007; Evanschitzky et al., 2012). This calls for new

theoretical approaches to better capture the underlying nature of NPD success factors (Evanschitzky et al., 2012).

NPD research can achieve more thorough better understanding of success factors, while controlling for three central contingencies: (1) separate NPD stages (Lee et al., 2008; Lewis et al., 2002; Naveh, 2005), (2) specific open innovation settings where multiple firms are involved (Evanschitzky et al., 2012; Rese and Baier, 2011) and (3) specific industries (Balachandra and Friar, 1997).

NPD research has investigated success factors in the separate stages, mainly focusing on idea generation and the early development stages of the new product (Aagaard and Gertsen, 2011; Markham, 2013; Robbins and O'Gorman, 2014). Research has only marginally addressed the testing and validation stage (Cooper, 1990). In this late development stage, implementation characterised by structured coordination, standardisation and controlled efficiency overcomes the importance of innovation triggered by the flexibility and freedom typical of the early development stages. Thus, the late development stage is fundamentally different from the early development stages. Moreover, the late development stage is important because before entering the market new products are often tested with customers to collect information in order to adjust and perfect the products. Testing the new product with customers in this late development stage is precursor of more successful product launches on the market (Barczak et al., 2009; DiBenedetto, 1999). Hence due to its difference and importance, the late development stage cannot be overlooked and requires investigation. This late development stage demands at least the same attention as idea generation and the early development stages and NPD success can be defined in this stage as well.

In recent decades a more open innovation setting has characterised NPD. Firms are increasingly collaborating with external partners, due to the increasing complexity of new products and the development process (Bhaskaran and Krishnan, 2009; Knudsen, 2007). Given the complexity of radical projects, more than half of such projects involve collaboration with partner organisations (Barczak et al., 2009). Many firms engage in multiple partnerships to develop new products. Due to the rising complexity of their partnership network, these firms increasingly involve intermediaries to handle this complex network of partnerships (Howells, 2006; Tran et al., 2011). However, in NPD half of inter-firm partnerships fail (Bleeke and Ernst, 1993; Sadowski and Duysters, 2008; Spekman et al., 1996) and empirical evidence of the impact of inter-

firm networks on NPD hard fact performance is limited (Hoang and Rothaermel, 2005; Knudsen, 2007). Moreover, how and under which conditions intermediaries add value to firms remains unclear (Howells, 2006; Tran et al., 2011).

Most of the recent NPD studies are based on multi-industry samples, where data is collected by survey from a number of firms (Barczak et al., 2009; Cooper and Kleinschmidt, 2007). NPD studies focusing on a specific industry could provide finer-grained insight to guide NPD management research (Balachandra and Friar, 1997).

The late development stage in the pharmaceutical industry offers the opportunity to control for these three contingencies in NPD. In the pharmaceutical industry the late development stage corresponds to clinical trials – when the candidate drugs are tested on humans. Besides being highly expensive and time-consuming, clinical trials are characterised by a high failure rate (DiMasi et al., 2010; Gassmann et al., 2008; Kaitin and DiMasi, 2011). In clinical trials, to approve the market entrance of the drugs regulatory authorities impose that pharmaceutical companies have to enter into partnerships with hospitals for clinical testing. Moreover, in recent decades pharmaceutical companies have been increasingly involving intermediaries, called Contract Research Organisations (CROs), to manage their partners on development tasks (Azoulay et al., 2010; Piachaud, 2002). Though CROs offer a number of benefits they can potentially alter the partnership between pharmaceutical companies and hospitals (Azoulay et al., 2010; Getz and Vogel, 2009; Piachaud, 2002). The relationships among pharmaceutical companies, hospitals and CROs can be described as a complex partnership network.

By taking a contingency perspective this study investigates NPD success and failure in the late development stage in the pharmaceutical industry. It examines the partnership networks of the stakeholders involved by integrating relational view, network theories and literature on intermediaries. This research introduces new streams of literature to study NPD, which have the potential to contribute value in understanding the complex phenomena of NPD success and failure. Thus, the primary aim of this PhD project is to better explain the success and failure of new pharmaceutical products in clinical trials by studying the network in which pharmaceutical firms, hospitals and contract research organisations are embedded. This overall research aim can be sub-divided into the following questions:

- What causes success and failure in clinical trials?

- Can such causes of success and failure be systematically mapped?
- Does the assessment of clinical trial success and failure provide insights into a more general concept of NPD success and failure during later stages of the development process?
- What is the role played by partnership network characteristics such as prior history, exclusivity, and proximity in defining NPD efficiency?
- What is the moderating role of intermediaries on the effects of prior history, exclusivity, and proximity on NPD efficiency?

Literature Review

This section illustrates the theoretical foundations of this PhD study. The research topic is at the confluence of different lines of research: NPD literature, contingencies theory and inter-organisational studies stemming from the relational view in the alliance literature, network theory and literature on intermediaries. The theoretical contributions of this thesis derive from the combination and the extension of these different lines of research.

NPD literature lacks original theory (Ernst, 2002; Evanschitzky et al., 2012; Hauschildt and Salomo, 2007) and might have overlooked or not yet identified some factors that can help explain NPD success (Cooper and Kleinschmidt, 2007; Evanschitzky et al., 2012). Therefore, NPD literature calls for new theoretical approaches to better capture the underlying nature of NPD success factors (Evanschitzky et al., 2012). A theoretical approach is offered by contingency theory, which explains the relationship between NPD and its context and how this relationship influences NPD success. Depending on the context certain factors may lead to success or failure and differ widely in magnitude and direction (Balachandra and Friar, 1997).

NPD literature has mostly focused on the definition of success in the early development stages, neglecting the late development stage. In light of the increasing number of NPD inter-firm collaborations, the NPD literature also tries to identify which combination of network characteristics maximise the probability of NPD success. The relational view and network theory offer interesting theoretical approaches to study inter-firm relationships. However, relational view theorists fail to further encompass the embeddedness of the firms and their partnerships in a larger contextual network of relationships, and social network studies have not answered

questions at the firm-level regarding strategies, behaviours and processes (Dhanaraj and Parkhe, 2006). Moreover, firms have begun to work extensively with innovation intermediaries, although little knowledge exists about the relationship between innovation intermediaries and their clients (Howells, 2006; Pittaway et al., 2004; Verona et al., 2006) and little is known about when and how innovation intermediary capabilities add value to clients' NPD processes (Tran et al., 2011).

This PhD study investigates NPD success and failure on a range of contingent factors such as late development stage, inter-organisational open innovation setting and specific industry. This research better explains the success of new products in the late development stage by studying the network in which firms, partners, and intermediaries are embedded.

This PhD study makes several important theoretical contributions. First, this study looks at success and failure factors in NPD by taking in a contingency perspective. Hence, this research answers the call for new theoretical approaches to better capture the nature of NPD success factors. Second, this study advances research in NPD by identifying success and failure factors in late development stages in specific industry and inter-organisational open innovation setting. Beyond traditional success factors from NPD studies synthesised in meta-analyses and reviews, this study identifies a set of additional success factors relevant in the late development stage. Third, the study specifically focuses on network-related success factors in late development, which have mostly been overlooked in the NPD literature. By studying the structure effect of network-related factors on the success of the late development stage, this study shows that inter-firm partnerships in NPD play a significant role. Fourth, the study extends the relational view theory by integrating network theories focusing on the structures of the network and contributes to a deeper understanding of inter-organisational competitive advantage. Finally, this study addresses intermediaries as an emerging phenomenon in inter-firm NPD and moves forward from previous studies by investigating whether intermediaries add value to the client firm.

Methodology

The pharmaceutical industry is the ideal domain of enquiry for this study. First, the pharmaceutical industry is strongly dependent on innovation for growth (Gassmann et al., 2008; Sabatier et al., 2012), thus the NPD process is central and more complex in the industry than in other industries. Second, external authorities clearly and

uniformly define the different stages of the NPD process and all pharmaceutical NPD projects must pass through the same development stages. This allows to study NPD projects at the same stage of development across different firms in the industry. Finally, the pharmaceutical industry can be a model for other industries as it copes with an ever-changing competitive environment by combining a high level of specialised knowledge and innovation (Henderson, 1994). The research methodology of this study is divided into two main steps: a qualitative expert study divided into data collection, data analysis and validation and a quantitative study with the statistical model used.

Qualitative data was collected in an expert study to explore additional managerial causes of clinical trial failures emerging from practice and identify success factors in clinical trials. Qualitative expert studies are useful to analyse tendencies at the macro level and to access and understand practitioners' visions (Hansen et al., 2009). 17 face-to-face interviews were conducted with experts in clinical trials in Denmark and Italy between 2010 and 2012. The experts worked in pharmaceutical companies, CROs, clinical development solutions providers and clinical sites. The chosen interviewees had 10–40 years of experience in the pharmaceutical industry.

The interviews were semi-structured with open-ended questions and followed a common set of questions. Initially, the interviewees were guided to reflect on the contingencies of clinical trials and how these factors influence the testing process. Next they were asked to broadly discuss the journey of a drug candidate through clinical trials in three physical settings: at the sponsor, at the local affiliate of the sponsor (or of the sub-contractor), and at the site. Interviewees were asked about challenges and problems in the management of clinical development and the reasons for failures in clinical trials, excluding purely drug-related reasons. They were encouraged to reason why certain clinical trials were more successful than others. They were asked about successful outcomes and how these were achieved. We defined success as succeeding in transitioning a drug candidate from one clinical trial phase to the next until the launch to market. As the interview progressed, most of the interviewees themselves raised additional or complementary issues. The interviews lasted 1-2 hours and were continued until the level of theoretical saturation was reached (Eisenhardt and Eisenhardt, 1989; Glaser and Strauss, 1967).

A thematic analysis of the interviews (Riessman, 1993) was adopted as a method to condense the data collected and simplify it and abstract it to identify common themes

and patterns (Miles et al., 2014). As in a qualitative studies, data collection, condensation and analysis are parts of a cyclical process (Miles et al., 2014), an interactive refinement and validation process was conducted. The management issues for failure drawn from earlier interviews were presented to later interviewees for member checking after they completed their own interviews. Member checking is a method to improve the external validity of the data (Guba and Lincoln, 1985). The critical managerial issues in the failure of clinical trials, the supporting data, contingencies and empirical findings were displayed in a content-analytic summary table (Miles et al., 2014). Finally, the identified management issues for failure were classified in a comprehensive conceptual framework.

The data has been further analysed to answer the research questions related to the success factors in clinical trials. Themes relating to success factors arose from the analysis. In this case the validation process of the identified factors was conducted by interviewing other clinical trial experts. A second round of 10 face-to-face interviews with experts in clinical trials was used to collect further evidence and validate the relevance of the success factors identified through the thematic analysis. The sample of interviewees was selected following the same selection criteria used for the first sample of interviewees. The interviews were conducted in Denmark in 2013. A long list of success factors was identified.

The network-related success factors identified in the qualitative part of the study inspired hypotheses on the influence of partnership network characteristics on NPD success conceptualised as NPD efficiency. These hypotheses were grounded in the combination of different theoretical perspectives in the field of inter-organisational NPD studies: the relational view, network theory and literature on intermediaries.

Quantitative relational data about the late development stage in the pharmaceutical industry was required to test these hypotheses.

The Pharmaceutical Investigators Cost Assessment Service (PICAS) database provided by Medidata Solution, Inc. is a large proprietary dataset that contains fine-grained objective longitudinal clinical trial data. The PICAS database contains 27,500 clinical study protocols of sponsor-initiated trials and more than 260,000 negotiated grant agreements between 200 sponsors and sites, collected between 1985 and 2010. The eventual involvement of CROs in the partnership between the sponsor and the site is also indicated. The clinical study protocols cover all therapeutic areas across all clinical trial phases. The representativeness and accuracy of the data was checked by

comparing the clinical trials in PICAS with the number of trials registered on the public database clinicaltrials.gov with the same sponsors within the same timeframe. The clinical study protocols collected in the PICAS database correspond to 33 % of all the trials performed globally in the same period of time and the sample includes most of the pharmaceutical firms that constitute the core of the global industry, heavily centred in the United States.

The variables were operationalised both at the relational level sponsor-site and at the level of the ego-network of the sponsor and of the site based on social network analysis measures. Due to the multilevel structure of the data (clinical trial partnership data nested within study protocol data, nested within a specific year and phase), a multilevel modelling approach addressing fixed and random effects was employed to test and quantitatively assess the conceptually derived hypotheses.

Findings and discussion

Managerial failures and causes of failure at the late development stage

The paper *Pharmaceutical new product development: why do clinical trials fail?* aims to answer the research questions on failure. From the clinical trial literature and expert statements in accordance with contingencies in clinical trials, the paper reveals seven critical management issues causing failures in clinical trials: difficulties in subject recruitment for testing, lack of experience in choosing and monitoring partners, lack of feasibility of the testing procedure, rigorous demands for documentation, too many incidents while testing, unmanageable portfolio complexity and incorrect assessment of market potential or returns.

The identified critical management issues are systematically classified in a comprehensive conceptual framework which advances understanding of failure and its causes in the late development stage when a new product is tested. The conceptual framework shows how different causes of failure define different types of failure by distinguishing between product and project failures and accounting for contingencies in clinical trials. The framework classifies failures into three different types: positive/inevitable failures, false-negative and false-positive. Positive/inevitable failures are caused by drug-related technical and economic causes (toxicity, lack of efficacy, problems with the pharmacokinetics and economics) and are necessary to foster innovation and create important value at the firm level.

False-negative and false-positive failures correspond to poor management decisions. These poor management decisions come from measurement errors such as termination of a project before the completion of a potential marketable product (false-negative failure) or completion of a project with no potential product (false-positive failure). These managerial failures are caused by identified critical management issues and should be avoided as they waste potential products and resources.

The conceptual framework provides insight to advance our understanding of failure in clinical trials into a broader concept of failure. The identified critical management issues can apply to other late development stages in other industries sharing some of the same contingencies. Moreover, classification of the failures can be used as a platform to investigate failures at other stages of NPD (e.g. initial screening or business case preparation).

It is interesting to notice that among the identified critical management issues the lack of experience in choosing and monitoring partners is related to the network of stakeholders involved in the testing. This issue indirectly underlines the importance of a network in which the stakeholders are embedded and is connected to other critical management issues through a chain of causal relations. When the firms (pharmaceutical companies) lack experience in choosing the right partners (hospitals and CROs) to test new drugs and their developed testing procedure is complex, subject recruitment for testing is often chaotic and slow. Choosing poor subjects and delaying subject recruitment extends product testing and complicates management of the entire portfolio of projects. Firms facing unmanageable portfolio complexity and partners struggling with subject recruitment can lower the quality of registered data. Mistakes and imprecision can drastically influence testing results and compromise reassessment of the market potential of a product or be the cause of serious adverse events and incidents.

In sum, interdependencies among critical management issues highlight the importance of a well-functioning partnership network of stakeholders in avoiding failure in the late development stage.

Success factors for the late development stage

Building on the findings of the explorative study on failures in the late development stage, the paper *Success Factors for the late development stage in NPD: Clinical trials as front-runner* unravels the success factors in the late development stage. The

paper employs a contingency perspective for identifying NPD success factors. These managerial approaches are necessary to achieve the fit between external contingencies and organisational structural characteristics that lead to high performance. They guide the organisation's ability to adjust or adapt to the environment and achieve success. The paper explores the critical managerial factors driving success in the context of different contingencies such as a specific type of industry, stage of the NPD process and open innovation setting. Specifically, the paper investigates success factors for the late development stage in NPD in the pharmaceutical industry characterised by an open innovation setting where multiple firms are involved.

A set of 32 success factors for the late development stage in the pharmaceutical industry emerged from 27 semi-structured face-to-face interviews with experts in clinical trials. Comparing the identified success factors with traditional success factors drawn from NPD literature reveals that some of the identified factors (12 out of 32) have mostly been overlooked in the literature. The paper finds six of these success factors have an underlying relational nature, which emphasises the network of relationships among the stakeholders involved in clinical trials. These network-related factors include good partner selection, past relationships between the sponsor and the site, limited shared partnership, goal alignment among actors, geographical proximity between the sponsor and the site and early involvement of CROs.

This group of network-related factors introduces a relational perspective to traditional success factors in NPD and indicates the characteristics of the network of partnerships among sponsor, site and CROs that drive success in clinical trials. The identification of this group of network-related factors is supported by the conclusions of a recent meta-analysis (Evanschitzky et al., 2012), that summarises the findings of NPD studies. Evanschitzy et al. (2012) pinpoint that the importance of traditional success factors is declining over time. It appears that new or not yet identified success factors could have emerged and be related to inter-organisational integration.

Network-related factors are becoming more important as the number of R&D partnerships increases (Hagedoorn, 2002). The dominant theories of the firm, the industry structure view (Porter, 1980) and the resource-based view (Barney, 1991; Wernerfelt, 1984), may not have a good fit with this empirical phenomenon as they focus on the intra-organisational level and not the inter-organisational network level (Rese and Baier, 2011). Therefore the findings of this paper not only identify the success factors for the late development stage in the pharmaceutical industry, but

emphasise a shift from the dominant intra-firm theories to alliance and network literature which look at the network of partnerships as a resource (Dyer and Singh, 1998; Tortoriello and Krackhardt, 2010).

Partnership network characteristics, NPD efficiency and the moderating role of intermediaries

The paper *A relational view on partnership efficiency in pharmaceutical new product development* extends the findings of the previous two papers. A conceptual model is developed based on the influence of network-related factors on NPD success, conceptualised as NPD efficiency in the late development stage. Moreover, the moderating role of the CRO is examined in the relationship between sponsor and site. The hypotheses are tested on longitudinal NPD partnership data in clinical trials. The results suggest how partnership network structures and intermediaries influence NPD efficiency in the late development stage in the pharmaceutical industry.

In the conceptual model, prior history, exclusive partnership, proximity among the partners, and intermediation are related to NPD efficiency. The findings suggest that prior history between the focal firm and its partner, exclusivity, and geographical proximity among the partners decrease NPD costs, while partners' prior history and cultural homogeneity among the partners increase NPD costs, thus negatively affecting NPD efficiency. Mediating a partnership between the focal firm and partner by involving intermediaries leads to efficiency losses. Intermediaries modify the structures of the NPD partnership network and alter NPD efficiency. Intermediaries moderate in particular the effects of prior history on NPD efficiency. The findings show there is little value in involving an intermediary if the focal firm and its partner share a long partnership history.

The tested hypotheses in the conceptual model were grounded in the combination of different theoretical perspectives in the field of inter-organisational NPD studies such as the relational view from strategic management literature, network theory from social network analysis and literature on intermediaries. Partnership network structures are investigated both at the dyadic transactional level between the firm and its partner and at the microstructural network level in which the dyad is embedded. The key identified structures reduce NPD costs as they help firms building the relational capabilities needed to manage a complex network of partners. Thus, these

key identified partnership network structures should be incorporated in the relational view because these findings contribute to better understanding of the relational rent, which is the source of inter-organisational competitive advantage for the relational view. This study is part of the growing stream of research that combines insights from alliance literature and network theory (Ahuja, 2000; Dhanaraj and Parkhe, 2006; Zaheer et al., 2000). Additionally, this study contributes to the growing literature on intermediaries by explaining how intermediaries affect the relationships in which they are embedded.

From a methodological point this paper answers the most urgent and pressing call in NPD for longitudinal studies based on large objective panel data from multiple-national sources, which test for moderators and interactions (Page and Schirr, 2008; Pullen et al., 2012). The paper comprehensively answers the major methodological challenges in NPD studies by employing multi-level late development stage partnership data from the pharmaceutical industry from 1985 to 2010.

Conclusions

The results of this PhD thesis can be described in relation to the extant NPD literature and the late development stage. NPD studies have mostly focused on idea generation and the early stages of NPD (Aagaard and Gertsen, 2011; Robbins and Gorman, 2014; Markham, 2013), only a few studies have addressed the late development stage (Naveh, 2005; Pisano, 2006). The underlying rationale is that inputting many ideas and being successful in the early stages of NPD guarantees the market launch of successful new products (Reid and De Brentani, 2004). The early stages require opening up the process to new ideas, routines and risks. Flexibility is largely accepted and creativity encouraged because they encourage new ideas and concepts. Partnerships are seen as means to maximise resources, co-develop technology and explore new markets (Kim and Wilemon, 2002).

In contrast, the late development stage narrows down ideas by testing and validating few products and controlling risk. The late development stage has mostly been identified with automatic implementation of testing and validation procedure, structured coordination and controlled efficiency (Lee et al., 2008; Lewis et al., 2002; Naveh, 2005). The information collected at this stage is highly relevant to adjust the product for market (Barczak et al., 2009), prime the market and create early adopters (Dolan and Matthews, 1993; Tidd and Bodley, 2002). In the late development stage

inter-firm relationships have mostly been neglected or have only been seen as a pragmatic solution to manage complex product testing.

This PhD thesis shows the relevance of inter-firm collaborations and the influence of partnership network structures on the success of the late development stage. Relationships with partners play a significant role for success at this stage, which has been previously neglected by NPD literature. This new relational perspective in the late development stage demands at least the same attention as idea generation and the early stages.

Bibliography

Aagaard, A., and Gertsen, F. (2011). Supporting Radical Front End Innovation: Perceived Key Factors of Pharmaceutical Innovation. *Creativity and Innovation Management*, *4*(4), 330–346.

Ahuja, G. (2000). Collaboration networks, structural holes, and innovation: A longitudinal study. *Administrative Science Quarterly*, *45*(3), 425–455.

Azoulay, P., Repenning, N. P., and Zuckerman, E. W. (2010). Nasty, Brutish, and Short: Embeddedness Failure in the Pharmaceutical Industry. *Administrative Science Quarterly*, *55*(3), 472–507.

Balachandra, R., and Friar, J. H. (1997). Factors for success in R&D projects and new product innovation: a contextual framework. *Engineering Management, IEEE Transactions on*, *44*(3), 276–287.

Barczak, G., Griffin, A., and Kahn, K. B. (2009). Perspective: Trends and Drivers of Success in NPD Practices: Results of the 2003 PDMA Best Practices Study. *Journal of Product Innovation Management*, *26*(1), 3–23.

Barney, J. (1991). Firm Resources and Sustained Competitive Advantage. *Journal of Management*, *17*(1), 99–120.

Bhaskaran, S. R., and Krishnan, V. (2009). Effort, Revenue, and Cost Sharing Mechanisms for Collaborative New Product Development. *Management Science*, *55*(7), 1152–1169.

Bleeke, J., and Ernst, D. (1993). *Collaborating to compete: using strategic alliances and acquisitions in the global marketplace*. New York: John Wiley & Sons Inc.

Cooper, R. G. (1990). Stage-gate systems: a new tool for managing new products. *Business Horizons*, *33*(3), 44–54.

Cooper, R. G., and Kleinschmidt, E. J. (2007). Winning businesses in product development: the critical success factors. *Research and Technology Management*, *50*(3), 52–66.

Dhanaraj, C., and Parkhe, A. (2006). Orchestrating Innovation Networks. *Academy of Management Review*, *31*(3), 659–669.

DiBenedetto, A. (1999). Indentifying the key success factors in new product launch. *Journal of Product Innovation Management*, *16*(5), 530–544.

DiMasi, J. A., Feldman, L., Seckler, A., and Wilson, A. (2010). Trends in risks associated with new drug development: success rates for investigational drugs. *Clinical Pharmacology & Therapeutics*, *87*(3), 272–7.

Dolan, R. J., and Matthews, J. M. (1993). Maximizing the Utility of Customer Product Testing: Beta Test Design and Management. *Journal of Product Innovation Management*, *10*(4), 318–330.

Dyer, J. H., and Singh, H. (1998). The relational view: Cooperative Strategy and Sources of Interorganizational Competitive Advantage. *The Academy of Management Review*, *23*(4), 660–679.

Eisenhardt, K. M., and Eisenhardt, M. (1989). Building theories from case study research. *Academy of Management Review*, *14*(4), 532–550.

Ernst, H. (2002). Success Factors of New Product Development: A Review of the Empirical Literature. *International Journal of Management Reviews*, *4*(1), 1–40.

Evanschitzky, H., Eisend, M., Calantone, R. J., and Jiang, Y. (2012). Success Factors of Product Innovation: An Updated Meta-Analysis. *Journal of Product Innovation Management*, *29*(S1), 21–37.

Gassmann, O., Reepmeyer, G., and von Zedtwitz, M. (2008). *Leading pharmaceutical innovation: trends and drivers for growth in the pharmaceutical industry*. Berlin Heidelberg: Springer Verlag.

Getz, K., and Vogel, J. R. (2009). Successful Outsourcing: Tracking Global CRO Usage. *Applied Clinical Trials*, 1–8.

Glaser, B. G., and Strauss, A. L. (1967). *The discovery of grounded theory: Strategies for qualitative research*. Chicago: Aldine de Gruyter.

Griffin, A., and Page, A. L. (1993). An interim report on measuring product development success and failure. *Journal of Product Innovation Management*, *10*(4), 291–308.

Griffin, A., and Page, A. L. (1996). PDMA success measurement project: recommended measures for product development success and failure. *Journal of Product Innovation Management*, *13*(6), 478–496.

Guba, E. G., and Lincoln, Y. S. (1985). *Naturalistic inquiry* (Vol. 75). Newbury Park: Sage Publications, Incorporated.

Gulati, R., and Gargiulo, M. (1999). Where do interorganizational networks come from? *American journal of sociology*, *104*(5), 1439–1493.

Hagedoorn, J. (2002). Inter-firm R&D partnerships: an overview of major trends and patterns since 1960. *Research Policy*, *31*(4), 477–492.

Hansen, E. G., Grosse-Dunker, F., and Reichwald, R. (2009). Sustainability Innovation Cube - a Framework To Evaluate Sustainability-Oriented Innovations. *International Journal of Innovation Management*, *13*(4), 683–713.

Hauschildt, J., and Salomo, S. (2007). *Innovationsmanagement.* Munchen: Vahlen.

Henderson, R. (1994). Managing Innovation in information age. *Harvard Business Review*, *72*(1), 101–105.

Hoang, H., and Rothaermel, F. T. (2005). The effect of general and partner-specific alliance experience on joint R&D project performance. *Academy of Management Journal*, *48*(2), 332–345.

Howells, J. (2006). Intermediation and the role of intermediaries in innovation. *Research Policy*, *35*(5), 715–728.

Kaitin, K. I., and DiMasi, J. A. (2011). Pharmaceutical innovation in the 21st century: new drug approvals in the first decade, 2000-2009. *Clinical Pharmacology & Therapeutics*, *89*(2), 183–188.

Kim, J., and Wilemon, D. (2002). Focusing the fuzzy front-end in new product development. *R&D Management*, *32*(4), 269–279.

Knudsen, M. P. (2007). The Relative Importance of Interfirm Relationships and Knowledge Transfer for New Product Development Success. *Journal of Product Innovation Management*, *24*(2), 117–138.

Lee, A. H. I., Chen, H. H., and Tong, Y. (2008). Developing new products in a network with efficiency and innovation. *International Journal of Production Research*, *46*(17), 4687–4707.

Lewis, M. W., Welsh, M. A., Dehler, G. E., and Green, S. G. (2002). Product development tensions: Exploring contrasting styles of project management. *Academy of Management Journal*, *45*(3), 546–564.

Markham, S. K. (2013). The Impact of Front-End Innovation Activities on Product Performance. *Journal of Product Innovation Management*, *30*(S1), 77–92.

Miles, M. B., Huberman, A. M., and Saldaña, J. (2014). *Qualitative Data Analysis: A Methods Sourcebook*. Thousand Oaks: Sage.

Montoya-Weiss, M. M., and Calantone, R. (1994). Determinants of new product performance: a review and meta-analysis. *Journal of Product Innovation Management*, *11*(5), 397–417.

Naveh, E. (2005). The effect of integrated product development on efficiency and innovation. *International Journal of Production Research*, *43*(13), 2789–2808.

Page, A. L., and Schirr, G. R. (2008). Growth and Development of a Body of Knowledge: 16 Years of New Product Development Research, 1989–2004. *Journal of Product Innovation Management*, *25*(3), 233–248.

Piachaud, B. S. (2002). Outsourcing in the pharmaceutical manufacturing process: an examination of the CRO experience. *Technovation*, *22*(2), 81–90.

Pisano, G. (2006). Profiting from innovation and the intellectual property revolution. *Research Policy*, *35*(8), 1122–1130.

Pittaway, L., Robertson, M., Munir, K., Denyer, D., and Neely, A. (2004). Networking and innovation: a systematic review of the evidence. *International Journal of Management Reviews*, *5-6*(3-4), 137–168.

Porter, M. E. (1980). *Competitive strategy: Thechniques for analyzing industries and competitors*. New York: Free Press.

Pullen, A. J. J., de Weerd-Nederhof, P. C., Groen, A. J., and Fisscher, O. a. M. (2012). Open Innovation in Practice: Goal Complementarity and Closed NPD Networks to Explain Differences in Innovation Performance for SMEs in the Medical Devices Sector. *Journal of Product Innovation Management*, *29*(6), 917–934.

Radas, S., and Bozic, L. (2012). Overcoming Failure : Abandonments and Delays of Innovation Projects in SMEs. *Industry and Innovation*, *19*(8), 649–669.

Reid, S. E., and De Brentani, U. (2004). The Fuzzy Front End of New Product Development for Discontinuous Innovations: A Theoretical Model. *Journal of Product Innovation Management*, *21*(3), 170–184.

Rese, A., and Baier, D. (2011). Success factors for innovation management in networks of small and medium enterprises. *R&D Management*, *41*(2), 138–155.

Riessman, C. K. (1993). *Narrative analysis*. *Sage Publications*. Newbury Park: Sage Publications, Inc.

Robbins, P., and O'Gorman, C. (2014). Innovating the innovation process: an organisational experiment in global pharma pursuing radical innovation. *R&D Management*, n/a–n/a.

Sabatier, V., Craig-Kennard, A., Mangematin, V., and Kennard, A. (2012). When technological discontinuities and disruptive business models challenge dominant industry logics: Insights from the drugs industry. *Technological Forecasting and Social Change*, *79*(5), 949–962.

Sadowski, B., and Duysters, G. (2008). Strategic technology alliance termination: An empirical investigation. *Journal of Engineering and Technology Management*, *25*(4), 305–320.

Spekman, R. E., Isabella, L. A., MacAvoy, T. C., and Forbes, T. (1996). Creating strategic alliances which endure. *Long range planning*, *29*(3), 346–357.

Tidd, J., and Bodley, K. (2002). The influence of project novelty on the new product development process. *R&D Management*, *32*(2), 127–138.

Tortoriello, M., and Krackhardt, D. (2010). Activating cross-boundary knowledge: the role of Simmelian ties in the generation of innovations. *Academy of Management Journal*, *53*(1), 167–181.

Tran, Y., Hsuan, J., and Mahnke, V. (2011). How do innovation intermediaries add value? Insight from new product development in fashion markets. *R&D Management*, *41*(1), 80–91.

Verona, G., Prandelli, E., and Sawhney, M. (2006). Innovation and Virtual Environments: Towards Virtual Knowledge Brokers. *Organization Studies*, *27*(6), 765–788.

Wernerfelt, B. (1984). A Resource-based View of the Firm. *Strategic Management Journal*, *5*(2), 171–180.

Zaheer, A., Gulati, R., and Nohria, N. (2000). Strategic networks. *Strategic management journal*, *215*(3), 203–215.