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Published in:

Conference proceedings of 21st International Product Development Management Conference

Publication date:

2014

[Link back to DTU Orbit](#)

Citation (APA):

Smed, M., Salomo, S., & Getz, K. A. (2014). New, but slow – technical newness challenges late stage development speed. In Conference proceedings of 21st International Product Development Management Conference European Institute for Advanced Studies in Management, Twente University.

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NEW, BUT SLOW – TECHNICAL NEWNESS CHALLENGES LATE STAGE DEVELOPMENT SPEED

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Abstract

The down-stream processes where new product prospects undergo pilot testing and adjustments before market launch can have significant impact on development speed. Previous literature has primarily pointed to firm traits as influential factors to speed. However, product specific measures such as technical innovativeness may be a critical factor when going through the crucial late stages of development. We have limited knowledge of the relation between product newness and the speed of NPD, and how this may be related to firm size and partnering strategies during development. Combining product traits with firm resources relevant to late stage development speed can enrich our understanding of time-to-market in the aim of improving this crucial measure of NPD.

The research model is tested on a dataset of all new drug developments approved for the US market 2000-2010. The results show that newness of a product, small size of a development company and partnering for external resources all increases the speed of late stage development speed.

The results show that technical innovativeness of products in late stage development has the consequence of extending this important process of NPD. Also, partnering strategies as well as small development companies have a negative effect on the speed of late stage development. These results have the implications to managers, that in the case of developing technical innovative products, the allocation of resources in the development process should be considered accordingly.

Introduction

Speed of new product development is a crucial factor in product performance as this may diminish costs and contribute to competitive advantages (Gold, 1987; Mahmoud-Jouini, Midler, & Garel, 2004; Vesey, 1992). Especially in industries where patent life circles are an important pre-requisite for product performance the time to develop a new product is essential. Previous literature primarily focuses on firm level measures to study influential factors for development speed (Acur, Kandemir, De Weerd-Nederhof, & Song, 2010; Carbonell & Escudero, 2010; Jr, 1988). However, the technical innovativeness of a new product is a key measure in times where increased innovation is a preferred strategy for production firms.

Existing literature are not unanimous in the effect of product innovativeness on product success. Some studies point to a positive influence on market performance (Talke & Salomo, 2009; Zhou & Tse, 2005), where others show no effect between the two (Danneels & Kleinschmidt, 2001; Salomo, 2007; Mohan V Tatikonda & Rosenthal, 2000).

Common for studies on product newness is however the challenges such technical innovativeness have for new product development processes (Danneels & Kleinschmidt, 2001; Kock, Gemünden, Salomo, & Schultz, 2011). Technical innovativeness of new products bring by challenges of uncertainty often followed by a need to restructure internal resources and extend the available knowledge base (ibid).

As there are many differentiated results of technical innovativeness on success, but undisputed literature pointing to the challenges of innovativeness, it is relevant to connect innovativeness on development speed, which is a highly pursued strategy in production firms. A broader understanding of the development process of technical new products can increase managers knowledge applied for resource allocations strategies.

Existing literature on development speed is limited in the method of measuring time-to-market and product newness, as these measures are often subject to internal firm evaluation based on survey studies (Chen, Reilly, & Lynn, 2012; Lynn, Abel, Valentine, & Wright, 1999; McNally, Akdeniz, & Calantone, 2011). This paper is aiming to meet this gap by studying data from a product development process where external quantitative measures for development speed can be applied. In the Pharmaceutical industry new products undergo extensive testing before obtaining approval for market launch. After intensive laboratory research and animal testing, successful compounds enter the next stage of development, the clinical trial phases, where the new products are tested on humans. Here strict rules are being

followed, defined by regulatory authorities such as the FDA (US Food and Drug Administration) and EMEA (European Medicines Agency), who also give the final approval to the new products. New pharmaceutical products are therefore subject to external regulatory surveillance and final market approval leaving an external and objective measure of speed. The initiation date and termination date of drug testing are thus applied in this study.

Further, every new drug indication is connected to an original patent, which thereby supply quantitative patent data as a proxy for technical innovativeness. This study therefore apply a dataset off all new approved drugs on the US market between 2000-2010 measuring the time of the critical development phase of clinical trials before market launch connected to the original patents of the drugs.

Along side the aim of decreasing development time of the demanding clinical trials, the pharmaceutical industry is highly focused on technical newness. Introducing blockbuster drugs to the market mainly covers the large R&D expenditures (blockbusters = a drug with annual revenue of at least \$1 billion (Gassmann, Reepmeyer, & von Zedtwitz, 2008) and with a large number of existing treatments on the market there is a need to develop truly new drug candidates in order to be approved. The industry are therefore pursuing two primary strategies; 1) decreasing time-to-market of development in order to decrease the high R&D budgets, and 2) the discovery and development of technical new products to the market in order to reach blockbuster status of new drug candidates.

Even though this two sided strategy are a key issue in pharmaceutical product development the focus on both time-to-market and product innovativeness are issues easily generalized to many other industries, which is also prevalent in the vast amount of literature on both areas (Chen et al., 2012; Kock et al., 2011). This follows the challenges in the literature on development speed, which are not unanimous in determining a relationship between market success and developments speed; Some literature support the notion that speed prospers market success (R. Calantone, Garcia, & Dro, 2003; González & Palacios, 2002; Lynn et al., 1999), which follow the challenge of introducing new products on the market fast in order to exploit the patent life cycle. However, speed may also come at some costs, and literature therefore also suggest that speed may not always be the most desirable strategy – or not the most important measure when aiming at market success (Chen et al., 2012; Cooper & Kleinschmidt, 1994). This study aims at gaining further understanding of the relationship between development speed and technical innovativeness. As much literature on technical innovativeness suggests a highly challenging development process it is relevant to study if this will be at the expense of speed. This study therefore builds on the notion, that speed may

not always be the most prevalent strategy; the innovativeness of the product under development may create circumstance, which create difficult circumstances for optimization of development speed.

In order to enrich the research model a proxy for the internal resources available at the firm, and the external strategy applied in relation to external technology sourcing are applied. The relation between 1) firm size, and 2) partnering level on development speed are thus studied. Integrating these measures in the research model can indicate if firm size and partnering as proxies for internal and external resources influences development speed when controlled for technical innovativeness.

Research model and hypothesis´

Much research have been conducted on the speed of NPD as a general process, or focused around the frond-end of development (Aagaard & Gertsen, 2011; Chen et al., 2012; Veryzer, 1998). The dependent variable here is development speed; an issue area which have been studied under different terminologies; time-to-market (MV Tatikonda & Montoya-Weiss, 2001), innovation time (Mansfield, 1988), project duration (Ulrich, Sartorius, Pearson, & Jakiela, 1993). The focus in this study is on development time, and therefore not on e.g. time from initial idea discovery until market introduction. This study focuses on the often-neglected later stages of development after initial idea generation and prototype development is finalized.

Literature on the development of technical innovative products have pointed to the challenges of preparing the organization for the new structures often needed when radical products are developed for the market (Danneels & Kleinschmidt, 2001; Kock et al., 2011). Radical innovations will often reach beyond existing capabilities in line with current portfolio, and thereby induce a need for complementary capabilities in order to extend the firms knowledge base (Teece, 1986, 1996). This knowledge base both refers to technical capabilities, but also market intelligence to support the new product application on the market. These activities relevant for technical innovative products are however relevant to study in relation to the important time-to-market measure, which is a key parameter for the NPD performance.

Technical innovativeness

Previous research has studied the impact of innovativeness on speed in the front-end of development (Aagaard & Gertsen, 2011). It is here recognized that radical new innovations have a longer front-end development time. Newness of a product is often followed by a high

degree of uncertainty, which leads to increased need of new information (Chen et al., 2012; Veryzer, 1998). Further, technological newness can bring by organizational challenges, as new competences and processes might be needed in order to develop this new product to the market (Kock et al., 2011; Teece, 1986).

This technological uncertainty that follows product newness can thereby result in longer development time (Gupta, Raj, & Wilemon, 1985). The challenges of product newness are also applicable in the later phases of development where the new products are being tested before launch. It is therefore relevant to test if newness also influences the time after discovery and therefore the late stage of development.

The technical newness of a product candidate is in this study measured by patent citations. If a product has few or none backward citations in the patent application it is considered new to the market. This is in line with the above argument, that development of new products experience higher degree of uncertainty. If a patent has fewer backward citations, less previous knowledge can be drawn upon during the development of the new product. With a high level of references to previous patents it can be expected, that previous research projects have acquired information relevant for the new product development process. Technical newness defined by few backward citations thereby represents an opportunity to bring by something radical to the market. However, in the development of such technical new products there will be a need to extend the existing knowledge base and the resources available in relation to the existing portfolio. These efforts may extend the products time in development and thus have a negative effect on speed. We therefore hypothesis:

Hypothesis 1: Technical innovativeness has a negative effect on late stage development speed

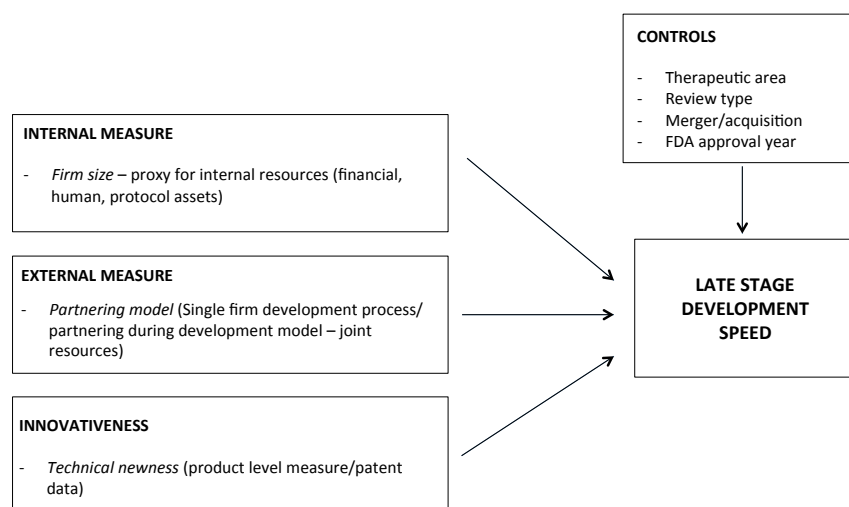


Figure 1: Conceptual framework

Company size

Company size has often been applied as a proxy for firms internal resources (Chandy & Tellis, 2000; Song, Im, Bij, & Song, 2011), as large companies will often have more extensive financial, human and portfolio assets than smaller firms. The large size of a company may result in organizational challenges such as increasing layers of management, which may challenge a process of innovation (Chandy & Tellis, 2000). This may especially apply in the front end of NPD, where new ideas are created and prototypes developed.

In the later stages of product development it has previously been recognized that large companies have advantages, as they have experience in the complex processes of product testing (R. J. Calantone & Benedetto, 2000; Danzon, Nicholson, & Pereira, 2005). Calantone and Benedetto (2000) point to market power as an influential factor in time-to-market. Market power is here defined as companies with strong brand equity or large companies with cost advantages. This study focuses on firm size in the perspective of late stage development.

Large companies can exploit that they have existing competences within the technologies and apply this experience in the resource demanding late stages of development (Danneels & Kleinschmidt, 2001; Danzon et al., 2005). We therefore hypothesis:

Hypothesis 2: *If the development company of the late stages of development is large, this will have a positive effect on the development speed.*

Partnering strategy

Previous studies on alliances in development processes have been pointing to the importance of a co-development strategy and formal management structures in order to obtain and sustain these positive outcomes of the relation (Mowery, Oxley, & Silverman, 1997; Powell, Koput, & Smith-Doerr, 1996). One of the central measures in such an alliance coordination strategy is a clear definition of the individual and joined tasks of the alliance partners (Das & Teng, 1998). This process may be complicated and issues such as decision proceedings, performance measures and common goals are also central measures in the success of co-development (ibid). These general challenges also apply to the approval process, as studies from the pharmaceutical industry points to some negative effects of alliances if especially small companies enters to many partnerships, as such firms may have a lack of resources to monitor and manage these collaborations (Deeds & Hill, 1996).

Previous research on development speed has primarily observed the whole process of NPD including idea generation, prototype development and testing. In this perspective partnerships in NPD may positively affect speed due to the complimentary capabilities mentioned earlier. However, as this study is exploring late stage development and the influential factors to product testing, partnerships may be representing some challenges to speed. As mentioned above partnerships also represent a coordination challenge, which is further enhanced in the regulatory heavy testing phases. In-house developed products here have the advantaged of easier coordination through the demanding prototype testing phases. We therefore hypothesis:

***Hypothesis 3:** If more than one company is involved in the testing process the development speed is longer*

Methodology and data collection

Previous studies of development speed are primarily based on data where speed measures is subject to internal review. Internal stakeholders are here asked their judgment of development speed in relation to related measures (R. J. Calantone & Benedetto, 2000; Lynn et al., 1999). This method is often applied while a measure of development time is difficult to identify and collect. This study has therefore chosen to focus on the Pharmaceutical industry, as the process applied here identifies initiation and approval markers for late stage development.

There are three central phases of clinical research in the testing process of new biotechnological or pharmaceutical drugs, i.e., phase I – III. The trials intensify with respect to the number of participants throughout the three phases. In phase I there are usually less than 100 participants (i.e. individuals involved in testing the new pharmaceutical product) where safety is the prime goal. Phase II requires 100 – 300 participants, and here longer-term effects and determination of exact dosage is the main aim. Phase III requires 1000 or more participants to be included in the trials, where the new product's effects are compared to an equivalent benchmark product (Hathaway, Manthei, Haas, & Meltzer, 2009, FDA¹; clinicaltrials.gov²).

¹ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm090410.htm>. Retrieved October 12th 2010

² Clinicaltrials.gov is an institutions under the US National Institute of Health supervising and documenting clinical trials. <http://clinicaltrials.gov/ct2/info/understand>. Retrieved October 12th 2010

During the development process of clinical trials the Pharmaceutical industry are in close contact with the regulatory authorities such as the FDA as these actors have the final decision power concerning new products approval. Before entering into the trial phases an IND – investigational New Drug application – is submitted and approved, and after the last of the three trial phases is conducted a NDA – New Drug Application is submitted to the authorities to obtain final market approval.

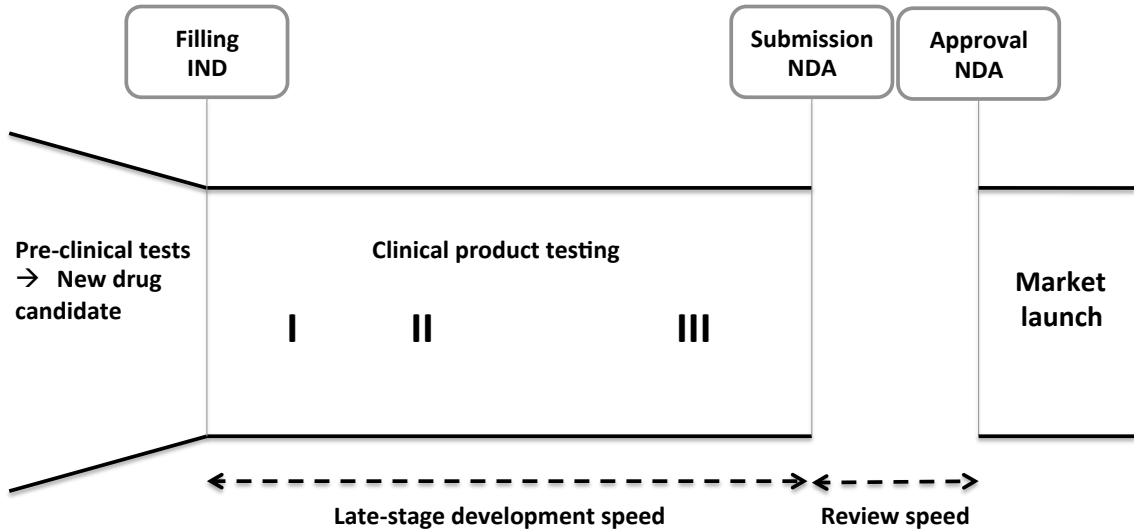


Figure 2: Process of late stage drug development. IND=Investigational New Drug, NDA=New Drug Application

To study the speed of product testing in the Pharmaceutical industry, data is collected for all approved drugs on the US market between 2000-2010. Here the IND time and the NDA time is identified and applied to measure the speed of late stage development. The speed of development measure is therefore not based on a subjective internal measure among internal firm actors. The dataset is a total of 230 subjects (all new approved drugs on the US market 2000-2010), and are further enriched by matching the drugs with data from R&D reports (R&D Focus), and patent data based on the original drug application.

Measures

Following is an overview of the measures applied in the regression model to test the hypothesis proposed in this paper.

Table 1: Overview of measures

Measure	Measurement method	Applied as
IND sub.	Year of Investigational New Drug (IND) submission	Applied to the development speed estimation
NDA Sub.	Year of New Drug Application (NDA) submission	Applied to the development speed estimation
Development speed	Time (months) from IND submission to NDA submission (numerical variable)	Dependent variable
Product newness	Backward citations of original patent (Numerical variable)	Explanatory variable
Firm size	Large = Top 50 of industry by revenue at development year (dichotomous variable)	Explanatory variable
Partnering	Single company development process or more than one partners during development (dichotomous variable)	Explanatory variable
Review type	Fast track (Priority) or not (dichotomous variable)	Control
Therapeutic area	Product specification – (Categorical variable -10 categories)	Control
M&A	Merger or Acquisition during development (dichotomous variable)	Control
FDA approval year	Year of FDA approval (Categorical variable -10 categories)	Control

Development speed: As the prototype testing phases in the Pharmaceutical is highly regulated it is possible to obtain the time of entering into testing – the clinical trials – and time of finishing clinical trials. Before entering into the clinical trial phases, firms have to submit an IND – Investigational New Drug application to the FDA. This applications includes results of the early stage discovery and laboratory testing results, and if accepted the drug can move on to the clinical trial phases. If the drug manage to succeed through the challenging 3 testing phases of clinical trials, the firm can submit an NDA – New Drug Application – and based on this obtain approval for the market. The dataset applied in this paper are all the approved drugs by the FDA between 2000-2010, and therefore all drugs with both an IND and NDA. The speed of development can thereby be calculated as the time from IND submission, to NDA submission.

Technical innovativeness: Technical newness of the product candidate going through the product testing process is measured by patent data. Each new product candidate is connected to an original patent, which can be identified in R&D reports. These patent numbers is subtracted and individual patent reports identified from the original patent database whether

filed at the USPTO, EPO or other databases, and therefore subtracted through the WHO database. From the patent reports the backward citations count is subtracted as a measure for technical newness of the new drug candidate. If a patent has few or no backward citations, and therefore is not referring back to previous innovations, it is defined as newer, than products with more backward citations, and therefore product candidates based on previous technological innovations.

Partnering: Companies enter into various alliances during development based on the prospect of the product candidate. It is therefore often observed that more than one company is active during the development phases of a new product, as firms look outside their own capacity to gain external resources for the development process. One partner may have discovered the new product and developed the prototype, and hereafter entered into a partnership with other firms in the aim of entering the product on the market. Other firms apply a strategy where the development process is based on internal resources alone and therefore a single firm strategy.

To measure whether the development is based on primarily internal resources alone, or a strategy based on incorporating external resources the partnering model for the individual drug development in the dataset is observed. The variable partnering therefore measures if the development process is based on a single company strategy or if more companies than one are integrated in the development process. R&D reports (R&D focus) for every drug candidate are manually studied and single firm strategy vs. multi firm development strategies indicated in the dataset. (0=single firm, 1=more than one firm)

Firm size: Firm size is defined as a measure of annual revenue in order to apply a measure, which both includes ongoing development processes and dynamics of the Pharmaceutical industry. If a sales measure were to be applied, it would have the risk of a skewed annual measure dominated by blockbuster products. Annual revenue also includes the R&D investments, which are a key cost in the pharmaceutical industry. To measure the size of the development firm it would not give a proficient picture to subtract size from a market report as of 2012. As the data set is based on product launch from 2000-2010 on the US market, the individual product launch data is applied to evaluate firm size. Annual revenue of the last 10 years (2000-2010) is therefore applied to evaluate size. These figures are applied from pharmaexec 50 – an annual market analysis of the top 50 Pharmaceutical (and Biotech) companies by revenue. This measure of firm size will give a more accurate and dynamic understanding of size of the involved companies in the individual product development processes. As the industry includes a large number of smaller firms the measure of size is

coded into a dichotomous variable where the top 50 are grouped in larger firms, and all others in smaller firms (0=small, 1= large).

Controls

Review type: As the demanding model of new product development is recognized in the pharmaceutical industry, initiatives has been engaged to speed up the process for some type of products. The fast track model was therefore initiated in 1998 to speed up the regulatory process for drugs treating life-threatening and serious diseases, by assigning more meeting with the FDA and reduced regulatory review time. When studying a dataset of new drugs on the US market it is therefore important to control for the type of review a drug is assigned. Every product in the dataset is therefore assigned a coding indicating whether the process is standard or priority (fast track), which is thereby controlled for in the analysis.

Therapeutic area: It is well known within pharmaceutical product development, that some disease areas have a more complex and therefore an average longer development time than others. Central nervous system is an example of a product/disease area, which per definition is complex, as central nervous system diseases and hereunder psychological illnesses often have a longer treatment period. The processes where new products are tested on humans are therefore often long in central nervous system diseases, and should therefore be controlled for. All drugs in the dataset is therefore categorized in ten therapeutic areas in line with common definitions in the industry and clinical research: Anesthetic, Anti-infectives, Anti-neoplastics, cardiovascular, Central Nervous system, diagnostic, endocrine, gastrointestinal, immunologic, respiratory

Mergers and Acquisitions: The Pharmaceutical and biotechnological industry are well known for its heavy activity of mergers and acquisitions over the years. Due to a substantial and continuous increasing cost of drug development mergers and acquisitions is a commonly used strategy in the industry. Large companies have the financial strength and experience in the extensive late stage clinical trials, whereas smaller development companies are challenged in the expensive testing phases, which is a main reason for the extensive M&As in the industry. It is therefore controlled for in this study, if a development company have been directly involved in a M&A during the development process. This information is found in the individual drugs development report in R&D Focus.

FDA approval year: The regulatory demands are continuously changing in the Pharmaceutical industry resulting in increasing protocol design complexity (DiMasi, Hansen, & Grabowski, 2003; Getz, Campo, & Kaitin, 2011). Further, the increasing cost and time spend on clinical trials have resulted in a change of the testing process model integrating more partners via outsourcing strategies and thereby increasing layers of management (Bodenheimer, 2000; Mehta & Peters, 2000). Including the year of approval as a control variable thereby controls for these vast changes in the business model of clinical trials over the years.

Table 2. Correlations of measures

	Dev. time	TA	Review type	M&A	FDA Yr	Firm size	Partnering	TechInn
Development time								
Therapeutic area	.05							
Review type	.07	-.21***						
M&A	.01	-.04	-.02					
FDA approval year	.03	.17* ²	-.08	-.01				
Firm size	-.18***	-.04	-.09	.26***	-.06			
Partnering	.11*	.09	-.19***	.18***	.03	-.04		
Tech. Inn.	-.13*	-.12*	.09	-.04	.03	.03	-.06	

*= $p < 0.1$, **= $p < 0.05$, ***= $p < 0.01$

Results and discussion

Technical newness pressures the time-to-market

The results of the regression analysis reveal that product newness has a negative effect on late stage development speed (table 3). We can thereby confirm hypothesis two as new products defined by patents citation patterns result in increasing development time.

Table 3: Regression model

Predictors	Model 1		Model 2	
	B	<i>t-value</i>	B	<i>t-value</i>
<i>Control variables</i>				
Therapeutic area	.036	.23	-.49	-.31
Review type	5.47	.65	8.13	.97
M&A	4.485	.55	3.86	.34
FDA approval year	1.4	.94	1.30	.91
<i>Explanatory variables</i>				
Firm size			-22.58**	-2.46
Partnering			18.40**	2.18
Technical innovativeness			-.76*	-1.66
R ²	.008		.085	
Adjusted R ²	-.012		-.052	
<i>df</i>	193		190	

*= $p < 0.1$, **= $p < 0.05$, ***= $p < 0.01$

The result illustrates a great challenge when developing really new products, with the possibility to be a first mover in the market. Besides the risk of failing product requirements, the development process is longer than products based on previous developments.

Interesting in this dataset is, that all of the drugs in the dataset are original new drugs, and therefore new to the market. All the products in the dataset are therefore new to the market, but the patent data analysis scale out how new these products are, and test this on the development speed. This study can thereby supply the industry with insights into the challenges of going through the long development process with a product not referring back to previous knowledge. Future studies should take these results and test, if this will also affect the final market success after launch.

More internal resources support speed of development

The results of the regression analysis show, that drugs developed in the alter phases by a large Pharmaceutical company have shorter development times. Drug development in the challenging late phases of development by one of the top 50 Pharma companies is faster through the prototype testing process, than drugs developed by small sized firms. This thereby confirms hypothesis 2, which argues, that larger companies have an advantage in later stages

of development, due to the vast amount of resources required (R. J. Calantone & Benedetto, 2000). Further, the experience large firms often have due to a broader portfolio is also an influential factor mentioned in previous literature (Danzon et al., 2005). Ongoing relations with key stakeholders is more likely with large companies, as they have more late stage clinical trials, and therefore opportunity to develop ongoing and close relationship to stakeholders. Another important actor in these stages is the regulatory authorities, which in the case of the US market is the US Food and Drug Administration (FDA). Previous literature also point to the importance of large companies experience in working with the complex regulatory requirements, and relations to the authorities. Previous research therefore indicates that large companies have an advantage in the later stage of development, where new products go through clinical trials. This study follows this line of argument and supports the advantages large companies experience in the demanding testing process.

Don't partner up for the sake of speed

The results of the regression analysis show a significant and negative effect of partnering on development speed. Therefore if more than one company is involved in a NPD process, the testing process is longer, than products development by a single company strategy. Companies whom have developed a new drug candidate all the way through the development process and through market launch experience a shorter development time. This result builds on the literature on partnering models and their influence on NPD processes (Mowery et al., 1997; Powell et al., 1996; van Beers & Zand, 2014). Partnerships are previously mentioned to have advantages in the front-end of NPD, where new products are being discovered and prototypes development, as companies with complimentary capabilities can join efforts in the complex drug discovery phase. However, in the later stages of development single company development have advantages, which influences the important speed to market. Single company development prevents the complex process of coordination, which is especially prevalent in relation to the highly regulated testing phases. In later stages single company efforts can speed up the process, by applying a less complex management structure, which often follow with partnerships in development. This is interesting in a time where much research point to the need for external resources in new product development. This result illustrate, that single company efforts is an advantage when undergoing a complex late stage development process, where adding to the complexity may extent the time to market.

Fast or new – the development trade off

Previous literature on partnering strategies point to patents, technology intake and prior experience as the main drivers for collaboration (Danneels & Kleinschmidt, 2001; van Beers & Zand, 2014). The motivations for partnering together with the technological capability intake challenges in cases of technological innovative products indicate that in cases of radical product development partnering can be a sound strategy to optimize missing capabilities.

The results of this study showing that both partnering and technological innovativeness is slowing down the development process supports previous studies on the challenges in developing radical products for the market. The purpose of this study is not to add to the literature on market success of radical products (Talke, Salomo, & Mensel, 2006; Zhou & Tse, 2005). This study instead supports the understanding that developing truly new products to the market follows a path of challenges, which will slow down the development process. When designing and allocating resources for development processes of radical innovations managers should therefore be aware of the often-extensive costs linked to such endeavors.

The single firm development process, which can stimulate the time-to-market challenge, may not be a preferable strategy when the aim is to support radical innovations where an extension of the existing knowledge base is needed. Partnering strategies are here a relevant strategy so support the need for complementary capabilities (Danneels & Kleinschmidt, 2001; van Beers & Zand, 2014) – especially in the cases where technical new products are being under development for market launch.

In the empirical context of this study – the pharmaceutical industry – the results show that large firms whom develop less innovative products in a singular firm strategy are faster at getting to the marketplace. It is here notable that all of products in the dataset are new to the market in the sense, that they are original products based on a patent life cycle. Follow-on drugs, which copy existing technical innovations, are not included in the dataset. All of the products in the dataset are therefore new to the market in order to get through the clinical trials and prove better than existing treatments. The results of this study however show, that within the frame of innovative products the most technical innovative and thereby the products referring to the fewest existing technical specifications will take longer to get through development than innovations which build on existing technologies. The information stored in the initiation idea discovery of the patent application can thereby tell pharmaceutical companies something about the resource allocation that they should consider in the later phases of product development.

Managerial implications

The results indicate that technical innovativeness of products in late stage development has the consequence of extending this important process of NPD. Also, partnering strategies as well as small development companies have a negative effect on the speed of late stage development. This together indicates that smaller firms who enter partnering strategies and apply technical new products in pilot-testing's are slower at entering the new product to the market. These results have the implications to managers, that in the case of developing technical innovative products it should be considered, that the speed of development will increase. When radical new products are discovered, which have few references to previous techniques, the allocation of resources in the development process should be considered accordingly.

Limitations

Testing speed dynamics on a sample on cases in the same industry is challenging to generalizations, but also decrease noise from market differences that may influence speed. The conclusions can thereby supply information, which is not effected by market diversity such as differences in market newness or development processes. This is different from many previous studies, which apply a cross industry dataset (Chen et al 2012). It should hover be noted that the data applied in this study represents an industry which in many cases may represent some unique traits. However, these traits also represent some unique research opportunities, as the highly controlled development process bring by an objective speed measure based on regulatory surveillance.

References

- Aagaard, A., & Gertsen, F. (2011). Innovation : Perceived Key Factors of Pharmaceutical Innovation, *20*(4), 330–346. doi:10.1111/j.1467-8691.2011.00609.x
- Acur, N., Kandemir, D., De Weerd-Nederhof, P. C., & Song, M. (2010). Exploring the Impact of Technological Competence Development on Speed and NPD Program Performance. *Journal of Product Innovation Management*, *27*(6), 915–929. doi:10.1111/j.1540-5885.2010.00760.x
- Bodenheimer, T. (2000). Clinical investigators and the pharmaceutical industry. *The New England Journal of Medicine*, *343*(7), 511. doi:10.1056/NEJM200008173430714
- Calantone, R., Garcia, R., & Dro, C. (2003). The Effects of Environmental Turbulence on New Product Development Strategy Planning, 90–103.
- Calantone, R. J., & Benedetto, C. A. Di. (2000). Performance and Time to Market : Accelerating Cycle Time with Overlapping Stages, *47*(2), 232–244.
- Carbonell, P., & Escudero, A. I. R. (2010). The effect of market orientation on innovation speed and new product performance. *Journal of Business & Industrial Marketing*, *25*(7), 501–513. doi:10.1108/08858621011077736
- Chandy, R. k., & Tellis, G. (2000). The incumbent's curse? incumbency, size, and radical product innovaiton. *Journal of Marketing*. Retrieved from <http://journals.ama.org/doi/abs/10.1509/jmkg.64.3.1.18033>
- Chen, J., Reilly, R. R., & Lynn, G. S. (2012). New Product Development Speed: Too Much of a Good Thing? *Journal of Product Innovation Management*, *29*(2), 288–303. doi:10.1111/j.1540-5885.2011.00896.x
- Cooper, R. G., & Kleinschmidt, E. J. (1994). Determinants of Timeliness in Product Development. *Journal of Product Innovation Management*, *11*(5), 381–396. doi:10.1111/1540-5885.1150381
- Danneels, E., & Kleinschmidt, E. J. (2001). Product innovativeness from the firm's perspective: Its dimensions and their relation with project selection and performance. *Journal of Product Innovation Management*, *18*(6), 357–73.
- Danzon, P. M., Nicholson, S., & Pereira, N. S. (2005). Productivity in pharmaceutical-biotechnology R&D: the role of experience and alliances. *Journal of Health Economics*, *24*(2), 317–39. doi:10.1016/j.jhealeco.2004.09.006
- Das, T. K., & Teng, B.-S. (1998). Between Trust and Control: Developing Confidence in Partner Cooperation in Alliances. *The Academy of Management Review*, *23*(3), 491. doi:10.2307/259291
- Deeds, D., & Hill, C. (1996). Strategic alliances and the rate of new product development: an empirical study of entrepreneurial biotechnology firms. *Journal of Business Venturing*,

6568(95), 41–55. Retrieved from
<http://www.sciencedirect.com/science/article/pii/0883902695000879>

- DiMasi, J. a, Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 22(2), 151–85. doi:10.1016/S0167-6296(02)00126-1
- Gassmann, O., Reepmeyer, G., & von Zedtwitz, M. (2008). *Leading Pharmaceutical Innovation. Trends and drivers for growth in the pharmaceutical industry* (2nd ed.). Berlin, Heidelberg: Springer.
- Getz, K. a., Campo, R. a., & Kaitin, K. I. (2011). Variability in Protocol Design Complexity by Phase and Therapeutic Area. *Drug Information Journal*, 45(4), 413–420. doi:10.1177/009286151104500403
- Gold, B. (1987). Approaches to accelerating product and process development. *Journal of Product Innovation Management*, 4(2), 81–88. doi:10.1016/0737-6782(87)90054-3
- González, F., & Palacios, T. (2002). The effect of new product development techniques on new product success in Spanish firms. *Industrial Marketing Management*, 31, 261–271. Retrieved from <http://www.sciencedirect.com/science/article/pii/S0019850100001504>
- Gupta, A. K., Raj, S. P., & Wilemon, D. (1985). The R&D-Marketing Interface in High-Technology Firms. *Journal of Product Innovation Management*, 2(1), 12–24. doi:10.1111/1540-5885.210012
- Hathaway, C., Manthei, R., Haas, J., & Meltzer, E. (2009). The Web of Clinical Trials Registration Obligations: Have Foreign Clinical Trials Been Caught? *Food and Drug Law Journal*, 64(2), 261–75.
- Jr, M. R. (1988). FROM EXPERIENCE faster new product development. *Journal of Product Innovation Management*, 3–6. Retrieved from <http://www.sciencedirect.com/science/article/pii/0737678288900069>
- Kock, A., Gemünden, H. G., Salomo, S., & Schultz, C. (2011). The Mixed Blessings of Technological Innovativeness for the Commercial Success of New Products, 28, 28–43.
- Lynn, G. S., Abel, K. D., Valentine, W. S., & Wright, R. C. (1999). Key Factors in Increasing Speed to Market and Improving New Product Success Rates. *Industrial Marketing Management*, 28(4), 319–326. doi:10.1016/S0019-8501(98)00008-X
- Mahmoud-Jouini, S. Ben, Midler, C., & Garel, G. (2004). Time-to-market vs. time-to-delivery. *International Journal of Project Management*, 22(5), 359–367. doi:10.1016/j.ijproman.2003.10.001
- Mansfield, E. (1988). THE SPEED AND COST OF INDUSTRIAL INNOVATION IN JAPAN AND THE UNITED STATES: EXTERNAL VS. INTERNAL TECHNOLOGY. *Management Science*, 34(October). Retrieved from <http://pubsonline.informs.org/doi/abs/10.1287/mnsc.34.10.1157>

- McNally, R. C., Akdeniz, M. B., & Calantone, R. J. (2011). New Product Development Processes and New Product Profitability : Exploring the Mediating Role of Speed to Market and Product Quality, *28*, 63–77.
- Mehta, S., & Peters, L. S. (2000). Competitive value may be created by as well as by R & D.
- Mowery, D. C., Oxley, J. E., & Silverman, B. S. (1997). STRATEGIC ALLIANCES AND INTERFIRM KNOWLEDGE TRANSFER, *17*(1996), 77–91.
- Powell, W. W., Koput, K. W., & Smith-Doerr, L. (1996). Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology. *Administrative Science Quarterly*, *41*(1), 116. doi:10.2307/2393988
- Salomo, S. (2007). NPD planning activities and innovation performance: the mediating role of process management and the moderating effect of product innovativeness. ... *Innovation Management*, 285–302. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1111/j.1540-5885.2007.00252.x/full>
- Song, M., Im, S., Bij, H. Van Der, & Song, L. Z. (2011). Does Strategic Planning Enhance or Impede Innovation and Firm Performance?*. *Journal of Product Innovation Management*, *28*(4), 503–520. doi:10.1111/j.1540-5885.2011.00822.x
- Talke, K., & Salomo, S. (2009). What about design newness? Investigating the relevance of a neglected dimension of product innovativeness. ... *of Product Innovation ...*, *26*(6), 601–615. doi:10.1111/j.1540-5885.2009.00686.x
- Talke, K., Salomo, S., & Mensel, N. (2006). A Competence-Based Model of Initiatives for Innovations. *Creativity and Innovation Management*, *15*(4), 060912022707001–???. doi:10.1111/j.1467-8691.2006.00402.x
- Tatikonda, M., & Montoya-Weiss, M. (2001). Integrating Operations and Marketing Perspectives of Product Innovation: The Influence of Organizational Process Factors and Capabilities on Development Performance. *Management Science*, (April 2014). Retrieved from <http://pubsonline.informs.org/doi/abs/10.1287/mnsc.47.1.151.10669>
- Tatikonda, M. V., & Rosenthal, S. R. (2000). Technology Novelty , Project Complexity , and Product Development Project Execution Success : A Deeper Look at Task Uncertainty in Product Innovation, *47*(1), 74–87.
- Teece, D. (1986). Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy. *Research Policy*, *15*(6). Retrieved from <http://www.sciencedirect.com/science/article/pii/0048733386900272>
- Teece, D. (1996). Firm organization, industrial structure, and technological innovation. *Journal of Economic Behavior & Organization*, *31*, 193–224. Retrieved from <http://www.sciencedirect.com/science/article/pii/S0167268196008955>
- Ulrich, K., Sartorius, D., Pearson, S., & Jakiela, M. (1993). Including the Value of Time in Design-for-Manufacturing Decision Making. *Management Science*, *39*(4), 429–447. doi:10.1287/mnsc.39.4.429

Van Beers, C., & Zand, F. (2014). R&D Cooperation, Partner Diversity, and Innovation Performance: An Empirical Analysis. *Journal of Product Innovation Management*, 31(2), 292–312. doi:10.1111/jpim.12096

Veryzer, R. W. (1998). Discontinuous Innovation and the New Product Development Process, 6782(97), 304–321.

Vesey, J. T. (1992). Put Speed in Product Development, 158, 151–158.

Zhou, K. Z., & Tse, D. K. (2005). The Effects of Strategic Orientations on Technology- and Market-Based, 69(April), 42–60.